B. Availability of Rulemaking Documents

An electronic copy of rulemaking documents may be obtained from the Internet by—

1. Searching the Federal eRulemaking Portal (*http://www.regulations.gov*);

2. Visiting the FAA's Regulations and Policies Web page at *http://www.faa.gov/regulations_policies* or

3. Accessing the Government Printing Office's Web page at *http://www.gpo.gov/fdsys/.*

Copies may also be obtained by sending a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–9680. Commenters must identify the docket or notice number of this rulemaking.

All documents the FAA considered in developing this proposed rule, including economic analyses and technical reports, may be accessed from the Internet through the Federal eRulemaking Portal referenced in item (1) above.

List of Subjects

14 CFR Part 27

Aircraft, Aviation safety

14 CFR Part 29

Aircraft, Aviation safety

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend chapter I of title 14, Code of Federal Regulations as follows:

PART 27—AIRWORTHINESS STANDARDS: NORMAL CATEGORY ROTORCRAFT

■ 1. The authority citation for part 27 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44704.

■ 2. Amend § 27.773 by revising paragraph (b) to read as follows:

§ 27.773 Pilot Compartment View

* * * * *

(b) If certification for night operation is requested, compliance with paragraph (a) of this section must be shown by ground or night flight tests.

PART 29—AIRWORTHINESS STANDARDS: TRANSPORT CATEGORY ROTORCRAFT

■ 1. The authority citation for part 29 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44704.

■ 2. Amend § 29.773 by revising paragraph (a)(2) to read as follows:

§ 29.773 Pilot Compartment View

(a) * * *

(2) Each pilot compartment must be free of glare and reflection that could interfere with the pilot's view. If certification for night operation is requested, this must be shown by ground or night flight tests.

* * * * *

Issued under authority provided by 49 U.S.C. 106(f), 44701(a), and 44703 in Washington, DC, on October 6, 2016.

Dorenda D. Baker,

Director, Aircraft Certification Service.

[FR Doc. 2016–24957 Filed 10–14–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 807

[Docket No. FDA–2016–N–2491]

RIN 0910–AG79

Electronic Submission of Labeling for Certain Home-Use Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to implement provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to require electronic submission of the device label and package insert of certain home-use devices when these devices are listed with FDA. FDA plans to make this device labeling available to the public through the Internet and would also provide search tools to facilitate locating information concerning a particular home-use device or a particular type of home-use device.

DATES: Submit either electronic or written comments on the proposed rule by January 17, 2017. In accordance with 21 CFR 10.40(c), in finalizing this rulemaking FDA will review and consider all comments submitted before the time for comment on this proposed regulation has expired.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by November 16, 2016; see section VI, the ''Information Collection Requirements'' section of this document. See section VIII of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions*): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–2491 for ''Electronic Submission of Labeling for Certain Home-Use Medical Devices.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your

comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_submission@omb.eop.gov.* All comments should be identified with the title, ''Medical Devices: Submission of Home-Use Device Labels and Package Inserts to FDA''.

FOR FURTHER INFORMATION CONTACT: Antoinette (Tosia) Hazlett, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5424, Silver Spring, MD 20993, 301–796–6119, email: *Tosia.Hazlett@fda.hhs.gov.*

With regard to the information collection: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

FDA is proposing to require certain medical device establishments listing devices under section 510(j) of the FD&C Act (21 U.S.C. 360(j)), if the device is labeled for home use, to submit the device label and package insert of such listed medical device, in the electronic format mandated in the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85), when the device is listed with FDA. (See section 510(p) of the FD&C Act.) FDA plans to make this device labeling information available to the public through an FDA-managed or partner Internet Web site.

B. Summary of the Major Provisions of the Proposed Rule

The electronic submission requirements of the proposed rule would be limited to only devices labeled for home use that are regulated by the Center for Devices and Radiological Health (CDRH) as class II and class III devices. For purposes of the proposed rule, a ''home-use device'' is any medical device that is labeled for use outside a professional health care facility. Sampling information indicates that this device group has a higher risk of misuse due to lost or misplaced labeling and operating instructions. In addition, the proposed rule would allow the voluntary electronic submission of device labels and package inserts for any class I home-use device or other home-use device not subject to the electronic submission requirements of the rule.

C. Legal Authority

FDA is issuing the provisions of this proposed rule that would implement the listing requirement for the submission of labels and package inserts for home-use medical devices under section 510(j) and section 701(a) (21 U.S.C. 371(a)) of the FD&C Act, which provides FDA the authority to issue regulations for the efficient enforcement of the FD&C Act. Section 510(p) of the FD&C Act requires that registrations and listings under section 510 be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver because the use of electronic means is not reasonable for the person requesting such waiver.

D. Costs and Benefits

FDA will use the existing FDA's Unified Registration and Listing System (FURLS) database and software systems to receive the submitted electronic labeling information and will bear the incremental cost of launching and maintaining the FDA-managed or partner Web site to display and make the submitted information available for the public to search and retrieve. The

benefits of this proposed rule would stem from a reduced incidence of adverse events due to the increased availability of medical device labeling. We estimate that the present discounted value number of people most likely to benefit from this rule over 10 years is 66.9 million, using a 7 percent discount rate, or 80.1 million, using a 3 percent discount rate. We estimate that the present discounted value of costs over 10 years would range from $48.5 to $51.7 million at a 7 percent discount rate and from $52.5 to $56.5 million at a 3 percent discount rate.

II. Background

A. Introduction

The Medical Device Amendments of 1976 amended section 510(j) of the FD&C Act to add requirements for registration of device establishments and listing of medical devices. Section 510(j) requires that every person who registers shall list all devices manufactured, prepared, propagated, compounded, or processed by him for commercial distribution. The statute provides that, for all devices subject to the listing requirement, the list must be accompanied by copies of the device label and, as defined in this proposed rule, the package insert. (See section 510(j)(1)(B)(ii) of the FD&C Act.) Our definition of ''package insert'' in this proposed rule would apply only to proposed subpart F. The statute also provides additional listing requirements for the submission of labeling and advertising for certain categories of devices (see section 510(j)(1)(A) and 510(j)(1)(B)(i) of the FD&C Act), which are not relevant to this proposed rulemaking.

When section 510(j) was added to the FD&C Act in 1976, and for many years thereafter, medical device registration and listing required the submission of paper forms to FDA. The forms had to be manually transcribed by FDA into its data systems, and the data stored primarily on reels of magnetic tape and floppy disks. There was no practical way for FDA to compile, update, or access the information submitted on these forms, much less provide routine public access to the information.

Taking these factors into consideration, when FDA proposed regulations regarding the device listing requirements, we explained that, instead of requiring the submission of ''information that FDA may not have immediate need for, and unless constantly updated by the owner or operator, would be out of date when needed,'' FDA by regulation would require that the owner or operator maintain a historical file of labels, labeling, and for restricted devices, advertisements, and make all or part of that file available to FDA upon request. (See 42 FR 52808 at 52809 (September 30, 1977).) That approach has remained in place since the final rule was issued in 1978 (43 FR 37990 (August 25, 1978)). The regulation made clear that FDA could require the submission of device labeling upon request by letter. Id.

In 2002, Congress recognized the technological and practical impact of the Internet when it passed the Medical Device User Fee and Modernization Act (MDUFMA) (Pub. L. 107–250). Section 206 of MDUFMA amended section 502(f) of the FD&C Act (21 U.S.C. 352(f)) to authorize electronic labeling for a device intended for use in health care facilities, provided the manufacturer afforded health care facilities the opportunity to request the labeling in paper form without additional cost. Section 207 of MDUFMA added section 510(p) to the FD&C Act, giving FDA the authority to collect registrations and listings ''by electronic means'' at such time as FDA determined it was feasible to receive such information through electronic means. In doing so, Congress observed the following:

> The Internet and increased computer usage have created a preference in many users for information for use applicable to prescription devices in electronic form. Even casual users of computers have become used to receiving electronic information . . . . The [legislation] conforms FDA practice to the norm by allowing manufacturers to provide healthcare facilities (such as hospitals, doctors' offices and clinics) labeling in this alternative medium . . . . This will better allow manufacturers to provide such facilities with information that is more robust, up-to-date, and user-friendly. . . . Given the increased reliance on computer usage, [MDUFMA section 207] requires manufacturers to provide registration information required under section 510 by electronic means . . . upon a finding by [FDA] . . . that electronic receipt of such information is feasible. . . .[1]

Subsequently, section 224 of FDAAA struck the language that required FDA to make a finding that receipt of electronic submissions ''is feasible'' and instead made the submission of registration and listing information by electronic means mandatory in all instances, except where FDA grants a request for waiver of the requirement for a person for whom electronic submission ''is not reasonable.'' (See section 510(p) of the FD&C Act.)

[1] H.R. Report. No. 107–728, at 41, 107th Cong., 2d Sess. (2002) (explaining MDUFMA sections 206 and 207).

This preamble explains how FDA is proposing to further implement sections 510(j) and 510(p) of the FD&C Act, by amending FDA's listing regulations to require the submission of electronic versions of the label and package insert for certain home-use medical devices when these devices are listed with FDA. For purposes of this proposed rule, the term ''home-use device'' would mean a medical device labeled for use in any environment outside a professional health care facility.

A ''professional health care facility'' is either (1) any environment where personnel with medical training are continually available to oversee or administer the use of medical devices, including, but not limited to, hospitals, long-term care facilities, nursing homes, emergency medical services, clinics, physicians' offices, and outpatient treatment facilities; or (2) a clinical laboratory. A ''clinical laboratory'' is a facility that (1) performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings; and (2) has been certified to perform such testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. 263a) in accordance with 42 CFR part 493, or is CLIA-exempt. These definitions of ''professional health care facility'' and ''clinical laboratory'' are only meant to provide guidance as to the application of proposed subpart F and are not meant for any other purpose, including the application of 42 U.S.C. 263a and 42 CFR part 493.

FDA is proposing that the home-use devices that would be subject to this proposed rule, if finalized, are those that are regulated by CDRH as class II or class III devices. This proposed rule would not apply to any class I devices, nor would it apply to devices regulated by the Center for Biologics Evaluation and Research (CBER), except to allow the voluntary submission of a device's label and package insert for such home-use devices under proposed § 807.220(a) (21 CFR 807.220(a)).

This proposed rule is intended to focus on higher-risk home-use devices. Under the FDA device classification system, the Agency classifies a device into a particular class based on the level of control necessary to provide a reasonable assurance of its safety and effectiveness, with class I requiring the least amount of control and class III requiring the most. (See sections 513(a)(1)(B) and 513(a)(1)(C)(i)(I) of the FD&C Act (21 U.S.C. 360c(a)(1)(B) and 360c (a)(1)(C)(i)(I)).) The proposed rule

focuses on class II and class III devices, which are considered moderate- to high-risk devices, and, except for permitted voluntary submissions, does not implicate class I home-use devices. By limiting implementation to these home-use devices, the proposed rule would focus on those types of home-use devices where patients, caregivers, and health care professionals have a significant need for quick and easy access to information to help ensure a device can be used safely to achieve its intended health benefits. Further, limiting the scope of the proposed rule to a small subset of important home-use devices will allow FDA to gain experience with the receipt, archiving, and dissemination to the public of electronic versions of device labels and package inserts before we consider any broader implementation, which should create efficiencies with regard to Agency resources.

B. Public Health Benefits

Home-use devices have significant public health importance to patients, caregivers, and health care professionals. But when used in an environment where a health care professional is not available to provide supervision and assistance, the Agency recognizes that these devices can present unique concerns and challenges (Ref. 1). In this preamble, we use the term ''patient'' to refer to any health care recipient, including someone who is not receiving care from a health care professional, *e.g.,* a person with a chronic condition who self-administers a treatment, or a person who receives care from a family member or friend. We use the term ''caregiver'' to refer to a person who provides voluntary help or care, *e.g.,* a family member, friend, neighbor, or acquaintance, and we use ''health care professional'' to refer to someone whose profession is in the health care sector, *e.g.,* a physician or a visiting nurse who provides care in the course of his or her duties. Because our use of these terms corresponds to their ordinary (plain language) meanings, we are not proposing regulatory definitions. In discussing patient labeling considerations for medical devices in general, we used similar terminology in ''Guidance on Medical Device Patient Labeling: Final Guidance for Industry and FDA Reviewers'' (Ref. 2).

Medical devices are different from other FDA-regulated medical products—*e.g.,* drugs and biologics—in that many devices are commonly intended to be used for many years and often do not have explicit expiration or recommended ''use-by'' dates. When a home-use device is used over a period of years, it becomes increasingly more likely that it may be separated from its original labeling or that its original labeling will not include current safety information or instructions for use. Additionally, home-use devices are much more likely to be used by lay users, who frequently have not been trained to use such medical devices and who are especially reliant on the instructions for use and other information provided by the device label and package insert. In contrast with use in professional health care settings, a patient or caregiver using a home-use device in a setting without professional oversight may not have extensive experience in the use of a device and may not have ready access to the original packaging or to alternative sources of information about a device.

Those people that use home-use devices are particularly vulnerable to adverse events because they may be inexperienced in the proper use and maintenance of the devices. In 2014, there were over 800,000 adverse events associated with medical devices. Our review of adverse reports that meet the criteria for faster level of review (Code Blue reports of deaths, fires, explosions, etc.) found, on average, three to five such reported events per week as having occurred in the home environment, *i.e.,* outside of a clinical facility. The Agency believes that device labeling information that would be submitted under this proposed rule and made readily accessible on an FDA-managed or partner Web site could reduce the incidence of adverse events when the labeling is lost or misplaced and the user is inexperienced with the home-use device, or when the labeling of the device has been updated with new information.

When a home-use device becomes separated from its labeling—and the user no longer has ready access to the important information provided in those materials, such as indications for use, contraindications, warnings, precautions, and instructions for setup, use, and maintenance of the device—the device user may be faced with serious obstacles to the safe and effective use of the device (Ref. 3). The absence of such critical information may lead to the device being used incorrectly, which could result in the delay of proper treatment or even injury to the patient. Improper use of a device can expose both the patient and caregiver to potentially serious risks—risks that could be avoided if information presented in the device's labeling was readily available. In addition, health care professionals, including emergency personnel who need to gain a rapid understanding of the operation and limitations of a device, may be left unsure as to how to best respond to a critical situation.

When the labeling that describes how to operate a device is missing, there is a higher chance that a device might be misused. CDRH has received reports of unavailable labeling for devices that could be dangerous when used by patients or caregivers outside a professional health care facility. For example, missing labeling for something as simple as a patient lift is dangerous when an elderly caregiver needs to understand how to assemble and safely operate the lift. Another example is a patient on home hemodialysis who needs to refer to available labeling for proper warnings and precautions, water type, or filters needed.

Although many manufacturers have Internet sites that provide information concerning the devices they currently market, those sites typically focus on newer products and often do not provide any information on devices that they no longer actively market. Sites also vary considerably in the types of information provided and may lack important details concerning their devices. Although some manufacturers' Web sites provide some labeling, FDA believes that most do not provide the label and package insert for all of their home-use devices listed with FDA.

The proposed rule would help to address these concerns by making it possible for FDA to establish an electronic database, published online and accessible to the public through the Internet, of labels and package inserts for listed home-use devices that would be submitted under this proposed rule. This database would fill an important gap in the information available to patients, caregivers, and the health care community concerning these home-use devices, and would allow both broad searches to identify legally marketed home-use devices that may fill a particular need and focused searches to obtain information concerning the use of a specific home-use device. In recent years, patients have become more involved in decisions concerning their health care, including the types of treatments they will undergo, the selection of specific home-use devices to be used in their treatment, and administration of the course of treatment (Ref. 4). This trend shows no signs of abating. With less day-to-day oversight by health care professionals, consumers have assumed responsibilities that have been traditionally borne by health care professionals. For example, consumers

may take on responsibility for setting up a home-use device, monitoring its performance, performing basic maintenance, and more. Because of this expanding role, consumers need to understand the risks and benefits of particular home-use devices in order to make informed decisions concerning their treatment options, and need ready access to information that will help them use devices properly, as intended by the manufacturers.

The FDA-managed or partner Internet Web site would provide a consolidated and easily accessible source of FDA database information concerning class II and class III home-use devices, including their approval or clearance status, intended uses, limitations, setup, and operation. The FDA database would not contain identifiable private information nor provide access to ''lock out'' information that is not included on the device labeling but is furnished through a source referenced in the device labeling, *e.g.,* information contained on a manufacturer's Web site, access to which is limited to professionals or some other restricted class of users. The FDA-managed or partner Internet site would contain links to other FDA information concerning the device, such as premarket submission information (*e.g.,* the summary of safety and effectiveness for a device), adverse event reports, alerts and notices, and recalls, as well as FDA information concerning the manufacturer. The information provided by FDA would help ensure greater safety and effectiveness of class II and class III home-use devices, particularly when a device has become separated from its labeling or when health care professionals, including visiting home nurses and emergency rescue personnel with varied skills and experience, need rapid access to information about unfamiliar products to help resolve a medical emergency. FDA would be able to make such information available from the time the device is first listed and, because the use of a device can continue long after a manufacturer ceases to market the specific device, we would continue to provide information even after the device is no longer marketed and no longer listed. FDA expects to provide search tools to facilitate locating information concerning a particular device or a particular type of device.

FDA also intends to make available the information collected under this rule through other partner Web sites that provide medical and health information to the public. For example, ''Daily Med'' (*http://dailymed.nlm.nih.gov*) is an Internet site administered by the National Institutes of Health's National Library of Medicine (NLM) that provides access to the labels and package inserts of prescription drugs. FDA believes that the public access to the labels and package inserts of the home-use medical devices covered by this proposed rule would provide a benefit similar to that provided by Daily Med in the drugs context.

C. Overview of the Proposed Rule

The proposed rule, if finalized, would implement provisions of sections 510(j)(1)(B)(ii) and 510(p) of the FD&C Act by amending FDA's listing regulations to provide that the label and package insert must be submitted electronically to FURLS, as part of the information required to list any home-use device regulated by CDRH as a class II or class III device. Section 510(j) requires manufacturers to list their medical devices and outlines the types of information that must accompany each listing. However, this proposed rule would apply only to class II and class III home-use devices regulated by CDRH, which represents a subset of devices that are subject to section 510(j) of the FD&C Act. For class II and class III home-use devices, the rule would amend the device listing regulations to provide that establishments listing such devices must submit to FDA a copy of the label and package insert of such home-use devices, when they are listed with FDA by electronic means, in an electronic format that we will specify and not as printed (paper) copies.

Unless a request for waiver is granted, all of the information submitted to FDA under the proposed rule would have to be submitted by electronic means, as required by section 510(p) of the FD&C Act, in a format to be specified by FDA that we can process, review, and archive. Initially, we intend to allow for the submission of labels and package inserts saved in Portable Document Format (PDF). The PDF format is a broadly used format that preserves both the content and appearance of a source document (such as a device label or package insert) and which can be read on all mainstream personal computers, regardless of the operating system, using freely available software. In addition, a wide variety of software packages and operating systems allow a source document to be saved as a PDF file. FDA believes that all listing establishments are already familiar with the PDF format, and that most already have the ability to save source documents as PDF files. We intend to make available additional information that will provide details and recommendations regarding this process by the time we publish a final rule.

At a later time, we expect to provide processes for the submission of labels and package inserts based on FDA's Structured Product Labeling (SPL) document standard. This would make it easier for FDA and the public to store, retrieve, and search information in home-use device labels and package inserts. We are considering at least two such processes—one process that would make it easy for a small business with limited means to submit SPL information by manually entering or uploading the information for one product at a time on an FDA Web page (this type of process is often referred to as a ''data entry'' process), and a second process that would provide an efficient way to submit SPL data for multiple devices in a single submission (this type of submission process is often referred to as a ''batch submission'' process). We intend to provide information explaining each process as it becomes available.

FDA plans to retain all labels and package inserts submitted under this rule in FDA's FURLS database. Not all information in the FURLS database is available to the public, so we intend to make the submitted labeling accessible to the public through an FDA-managed or partner Internet Web site, such as NLM, even after a device is no longer listed. However, if FDA bans a device under section 516 of the FD&C Act (21 U.S.C. 360f), we intend to remove any label and package insert from our FURLS database and from any other FDA or partner Web site we might use and replace those materials with a statement explaining that the device has been banned. If a device is recalled, we may add a notice to the labeling database, with additional information to help ensure the safe and effective use of the device, or advice to discontinue use of the device and additional steps to take to help ensure the health and safety of the patient or user of the device.

D. Public Participation in Setting the Scope and Objectives of the Proposed Rule

FDA used comments from the medical device industry, health care professionals, caregivers, and patients to help formulate the objectives and define the scope of this proposed rule. In September 2009, CDRH established the ''510(k) Working Group'' and the ''Task Force on the Utilization of Science in Regulatory Decision Making'' to address concerns about how well the 510(k) program (the primary regulatory route to market for medical devices) was meeting its public health goals of

facilitating innovation and assuring the safety and effectiveness of medical devices. As part of these reviews, FDA held two public meetings and three town hall meetings, solicited comments through three open public dockets, and met with many stakeholders over several months. In August 2010, CDRH released for public comment preliminary reports from these committees. The preliminary reports expressed concern regarding the lack of ready access to final device labeling and recommended:

- FDA should ''take steps to improve medical device labeling, and to develop an online labeling repository to allow the public to easily access this information.'' (Ref. 5)
- FDA should ''revise existing regulations to clarify the statutory listing requirements for the submission of labeling.'' (Ref. 6)
- FDA should ''explore the feasibility of requiring manufacturers to electronically submit final device labeling to FDA . . . and also to provide regular, periodic updates to device labeling, potentially as part of annual registration and listing or through another structured electronic collection mechanism.'' (Ref. 6)

The preliminary reports also recommended that if FDA requires submission of device labels, they be ''posted as promptly as feasible on the Center's public 510(k) database.'' (Ref. 6)

FDA received comments on these recommendations from industry, consumer, and health care professional groups. Some industry representatives expressed concern regarding the potential for disclosure of confidential or proprietary information. According to some industry representatives, device-specific information on device labels is not necessarily appropriate for the general public, but rather is intended for physicians or other health care professionals and may cause confusion if they are made available in a public database. Furthermore, industry suggested that the responsibility for disseminating labeling should rest solely with the manufacturer and should remain in the manufacturer's control. Industry also stated that many updates to labeling are made for marketing purposes and not related to regulatory requirements or device alterations.

Consumer and health care professional groups supported the recommendation of the 2010 510(k) Working Group and the Task Force preliminary reports. Their comments noted that providing access to online labeling resources would facilitate better-informed clinical decisionmaking.

In January 2011, FDA issued a ''Plan of Action'' outlining steps we will take to improve the 510(k) program and explaining our views and responses to comments we received concerning recommendations made in the August 2010 preliminary reports (Ref. 7). FDA agreed with comments that making labeling readily available could lead to better-informed clinical decisionmaking. Just as the FDA's central database for drug labeling conveys a public health benefit, we believe that a similar database for devices would be of significant benefit to the public health by providing useful information to health care professionals and patients. Although submission of labels and certain other labeling for all devices is a statutory requirement, FDA determined that it was important to seek additional stakeholder input at a public meeting before proposing any regulatory changes.

FDA held another public meeting in April 2011, specifically to discuss options, benefits, costs, and concerns regarding the collection of device labels and certain labeling and means of making the resulting information available to the public, including industry, health care professionals, caregivers, and patients (Ref. 8). Industry representatives did not support a system that would require submission of labels and other labeling for all devices to FDA, but generally agreed that there would be value in a more limited system, particularly with regard to devices intended for home use. Health care professionals and caregiver representatives were supportive of a broad system, but willing to consider any approach that would increase their access to reliable device information.

Reports by FDA's committees recommended that FDA fully implement section 510(j) by developing an electronic submission method for labels and package inserts for devices generally and many stakeholders supported the creation of a broad ''repository'' (essentially, an FDA-managed database accessible to the public through an Internet site) of labeling for *all* devices. However, FDA believes, at this stage, that the public health need for, and the opportunity to improve access to home-use device information call initially for the more-limited actions pursued in this proposed rule. In order to minimize risks and costs while we gain experience with implementing and managing electronic labeling, the Agency is limiting this proposed rule to only include the submission of labels and package inserts from home-use devices regulated by CDRH as class II or class III devices. As FDA and the public gain experience with the electronic submission of labeling and use of the planned searchable FDA-managed or partner Internet Web site, FDA will consider whether to implement this requirement for other categories of devices, or for devices generally.

FDA also conducted a series of followup focus group interviews of health care professionals to obtain their individual views concerning a wide variety of topics relating to medical device labeling, resulting in a series of reports, including ''Medical Device Labeling for Health Care Practitioners: Focus Group Study'' (May 2011) (Ref. 9) and ''Device Labeling Study: Practitioner Perspectives on Utility, Format, and Content of an Abbreviated Version of Labeling'' (March 2013) (Ref. 10). Participants saw considerable value in having device labeling available online for quick access when needed; participants noted that labeling that is not directly placed on a device—for example, a manual—can be hard to find when needed. Unlike a device label or package insert, information made available through the Internet is always readily available and cannot be lost or misplaced. Most participants favored having access to labeling through an Internet Web site, particularly if well-organized.

Additionally, in September 2015, FDA held a public meeting to discuss issues associated with medical device patient labeling that involved development, use, and access to device information (Ref. 11). At this meeting, many external stakeholders stated their belief that providing labeling in one place for consumers that is reliable and dynamic would increase accessibility to labeling for legacy devices and to labeling updates as new information becomes available for currently marketed devices. Also, while device information from other sources such as Web sites and YouTube videos may be useful, stakeholders indicated concern that some may be potentially erroneous and contain mostly promotional information.

III. Description of the Proposed Rule

A. Scope of the Proposed Rule

1. What devices would be subject to the proposed rule?

A device would be subject to the proposed rule if it is a ''home-use device'' as defined by proposed § 807.200, that is regulated by CDRH as a class II or class III medical device. Under this proposed regulation, a

''home-use device'' would be any medical device that is labeled for use outside a professional health care facility. Home-use devices that are co-labeled for, or can be used in a professional health care facility, would be subject to this proposed rule if the device is labeled for use in a patient's home or in any other environment that is not a professional health care facility.

Class I devices and devices regulated by CBER are not within the scope of the proposed rule, except for the authorized voluntary submission of a device's label and package insert for these home-use devices (under proposed § 807.220(a)). For more information about the definition of ''home-use device,'' please refer to section III.D.1 of this document.

2. When would a home-use device label and package insert have to be submitted to FDA?

Proposed § 807.205 would require the label and package insert of a home-use device subject to the proposed rule to be submitted whenever any provision within part 807 (21 CFR part 807) requires listing information to be submitted or updated. For example, the label and package insert would be required with such home-use device's initial listing required by § 807.22(a), with each annual listing under § 807.22(b), and whenever an action triggers a reporting requirement under § 807.28. If the label and package insert have already been submitted and have not been changed since they were last submitted to FDA, the establishment may simply certify that no change has been made to the previously submitted labeling; see proposed § 807.300(a). An updated label or package insert could be submitted voluntarily at any time; see proposed § 807.300(b).

3. Would every type of package insert regarding a home-use device have to be submitted to FDA?

No. The rule would limit the definition of ''package insert'' to include only those informational materials directed to the intended user of the device, and which are provided in a device package or which accompany the device when it is delivered to the user, including when already provided by electronic means. (See the proposed definition of *package insert* at § 807.200.) Only package inserts meeting this definition would have to be submitted to FDA. We have chosen to limit the scope of package insert in order to focus the proposed rule on those package inserts that are essential to typical intended uses and typical users of the home-use devices subject to this proposed rule. Examples of materials that would not be within the scope of the proposed rule include materials that are not intended for a patient (care recipient) or for the caregiver, health care professional, or family member who directly operates or handles the device or provides assistance to the patient in using the device, *e.g.,* an installation and calibration manual intended for technical or support personnel; supplemental training materials; supplemental service manuals; supplemental materials that concern optional additional uses that require accessories not included with the listed home-use device; and any supplemental materials that are made available only upon request or only upon payment of a separate fee.

4. Would the rule provide for the submission of advertisements or of labeling other than device labels and package inserts?

No. The proposed rule would not address the submission of advertisements or of labeling other than the device label and package insert.

5. Would the rule require any change to an existing label or package insert?

No. The proposed rule would not affect the form or content of home-use device labeling. Existing labeling requirements would continue to apply, including those of part 801 (Labeling) and § 809.10 (*Labeling for in vitro diagnostic products.*).

B. Submission of Device Labels and Package Inserts to FDA for Certain Home-Use Devices

1. Who would be required to submit labels and package inserts to FDA when listing a home-use device?

The owner or operator of an establishment (the remainder of this preamble will simply refer to ''the establishment'') that lists a class II or class III home-use device subject to this proposed rule would be responsible for submission of the label and package insert, just as the establishment is responsible for submitting all other listing information pertaining to the device. (See proposed § 807.205.)

2. How would labels and package inserts have to be submitted to FDA?

The proposed rule provides for the electronic submission of this information to FDA, as required by section 510(p) of the FD&C Act, in a form specified by FDA that we can process, review, and archive; see proposed § 807.205. Initially, FDA expects to specify saving the device label and package insert as PDF files and submitting those materials to FDA. Later, we expect to transition from submission of PDFs to submission of SPL-formatted information. We intend to publish information describing the entire proposed process by the time we publish a final rule. If a waiver from filing registration and listing information electronically has been obtained under § 807.21(b), the establishment would be required to submit the device labels and package insert called for in this proposed rule in the same manner as permitted for other registration and listing information covered by the waiver, as directed by § 807.34.

When the proposed rule is finalized, an establishment submitting a home-use device's label and package insert would confirm or provide the FDA-assigned premarket submission number of the device (§ 807.25(g)(4)) or the product codes for 510(k)-exempt devices (§ 807.25(g)(2)).

3. What would the consequences be of failing to submit the listing information identified in this proposed rule?

The failure to provide information required by section 510(j) of the FD&C Act, as implemented by part 807, including proposed subpart F, causes a device to be misbranded under section 502(o) of the FD&C Act and is a prohibited act under section 301(p) of the FD&C Act (21 U.S.C. 331(p)), which may result in seizure, injunction, or other penalties.

C. Dissemination of the Information Collected Under the Rule

1. How does FDA intend to make available the information collected under this rule?

FDA intends to make the labels and package inserts collected under this rule available on an FDA-managed or partner Internet Web site. We intend to link the labels and package inserts submitted under this rule to the listing record for the particular device. Over time, and as resources permit, we also intend to link each device listing to other FDA information, such as the device identifier required by FDA's unique device identification system, FDA premarket submission numbers, adverse event reports, and public health notifications, so that users of the planned FDA-managed or partner Internet Web site will also be able to access public information that is maintained in FDA's other databases concerning devices marketed or manufactured in the United States.

2. How will members of the public be able to find information collected under this rule and related FDA information concerning a home-use device?

We intend to provide several ways to search for information, such as the ability to search by:

- Proprietary name (for a specific device);
- Product code (for a generic type of device);
- Firm name (for all devices listed by a particular firm);
- FDA premarket submission number;
- Device identifier (the static portion of the unique device identifier required by §§ 801.20 and 801.40).

We also intend to provide a means to search the full text of labels and package inserts using free-form searches.

D. Proposed Amendments to Part 807

1. New Defined Terms

FDA is proposing to add definitions for two terms to part 807; these terms have not been defined in any prior medical device regulation: *Home-use device* and *package insert.*

Home-use device would mean a medical device that is labeled for use in any environment outside a professional health care facility. This definition is meant to make clear that ''home-use device,'' as defined in this proposed rule, would not be restricted in a literal sense to use in a patient's home, but is instead meant to take in a broader range of environments in which a device may be used outside of a professional health care facility.

If finalized, the definition of home-use device is meant to apply only to proposed subpart F for purposes of submitting the device's label and package insert when listing under section 510(j) of the FD&C Act. This proposed regulation would not apply for other purposes, including premarket submission determinations. Additionally, proposed § 807.200 would not apply for purposes of CLIA categorization under 42 CFR 493.15. The fact that a device would be considered a ''home-use device'' under this proposed regulation would not mean that the device has been ''cleared by FDA for home use'' within the context of 42 CFR 493.15, a regulatory provision related to the implementation of the CLIA provisions found at 42 U.S.C. 263a.

Package insert would mean all informational materials directed to the user of the device, and which are provided in a device package or which contemporaneously accompany the device when it is delivered to the user, including by electronic means. Although the term is used in section 510(j)(1)(b)(ii) of the FD&C Act (see the discussion of section 510(j) in section I. Background) and in various medical device regulations, this term is not defined in the FD&C Act or by any medical device regulation. A *package insert* is one type of device labeling. Our definition of ''package insert'' in this proposed rule would also apply only to proposed subpart F.

2. Conforming Proposed Amendment of § 807.26(e)

We would amend the first sentence of § 807.26(e) to strike the word ''only.'' This change is necessary to avoid conflict between the proposed regulatory amendments pertaining to the submission of labels and package inserts of home-use devices under new subpart F of this proposed rule and § 807.26(e), which states that owners or operators shall be prepared to submit such information ''*only* upon specific request'' (emphasis added). The submission of labeling for home-use devices that new subpart F of this proposed rule would require would not be responding to a targeted ''specific request'' for information under existing § 807.26(e). The proposed requirements to submit such information under new subpart F would conflict with § 807.26(e), as currently worded, but would not conflict with proposed § 807.26(e), as amended. FDA does not intend this change to result in a greater number of requests for information under § 807.26(e), and we do not intend to request the resubmission of information under § 807.26(e) that has already been submitted for home-use devices under new subpart F. Related § 807.26(f) prohibiting the submission of information requested under § 807.26(e) from ''using the FDA electronic device registration and listing system'' likewise would not apply to the information that would be submitted under proposed new subpart F if finalized, which provides instead for such information to be submitted ''in a format specified by FDA that we can process, review, and archive'' (proposed § 807.205).

3. Proposed Requirement To Submit the Label and Package Insert for Certain Home-Use Devices

We are proposing a new subpart to part 807, ''Subpart F—Submission of Labeling When Listing Certain Home-Use Devices.'' For establishments listing home-use devices subject to this proposed rule, proposed § 807.205 would require that the device label and package insert be submitted to FDA whenever any provision within part 807 requires submission of listing information regarding the device.

Proposed § 807.220 would make clear that the voluntary submission of the label and package insert of a home-use device that is not required under this proposed rule would be permitted. Proposed § 807.220(a) would make clear that for such devices, including a home-use device regulated by CBER, the owner or operator subject to part 807 could voluntarily submit the device label and package insert, which FDA could then make available to the public.

Proposed § 807.220(c) would make clear that the label and package insert for a discontinued home-use device could be submitted, which FDA could then make available to the public. This provision would provide a way for an establishment to make information about a discontinued home-use device available to the public, potentially reducing the burden of responding to requests for information about a discontinued device.

Proposed § 807.300 would explain when an updated device label and package insert must be submitted.

Proposed § 807.300(a) would reduce the burdens of the proposed rule, if finalized, following the initial submission of listing information to FDA by making it clear that resubmission of the label and package insert of a home-use device each year during the annual listing process, and in other circumstances when updated listing information must be submitted, would not be required unless changes have been made. Instead, if no change has been made to the most-recently submitted label and package insert, FDA would only require a statement to that effect. We expect this statement will be as simple as clicking a check-box within one of the processes FDA expects to provide.

Proposed § 807.300(b) would make clear that updated labeling information for a home-use device that is not required under this proposed rule, such as a CBER-regulated home-use device, could voluntarily be submitted at any time. We expect the majority of labelers will see advantages to keeping this information up-to-date, as a way of better serving current and potential users of their devices.

We would make a conforming amendment to § 807.40 to apply the requirements of proposed subpart F to listings by foreign establishments. This would ensure that both domestic and foreign establishments will be subject to the same requirements regarding the submission of labels and package inserts for home-use devices.

E. Effective Date

FDA is proposing that this rule would go into effect 90 days after publication of a final rule, if that results in an effective date prior to October 1 of the year of publication; otherwise, the rule would go into effect on January 1 of the year following publication of a final rule. This ensures adequate notice and avoids any possibility that a final rule might go into effect part way through an ongoing registration and listing cycle (October 1 through December 31 each year).

The proposed rule would implement provisions of the FD&C Act to require the submission of class II and class III home-use device labels and package inserts with device listing information submitted to FDA on or after the effective date of the rule. The rule would not be retroactive, and there would be no obligation to submit the label or package insert of a discontinued home-use device that was listed at any time prior to the effective date of a final rule; but if that device is listed during a subsequent registration and listing cycle (a cycle that begins after the effective date of a final rule), all listing requirements would have to be met, including submission of the label and package insert.

IV. Legal Authority

Section 510(j) of the FD&C Act requires all persons who register with the Secretary to file a list of all devices that are being manufactured, prepared, propagated, compounded, or processed by them for commercial distribution. The listing of all devices is required to be accompanied by a copy of the label, package insert, and a representative sampling of the labeling for such devices. (See section 510(j)(1)(B)(ii).) Accordingly, FDA is issuing the provisions of this proposed rule that would implement the listing requirement for the submission of labels and package inserts for home-use medical devices regulated by CDRH under section 510(j) and section 701(a), which provides FDA the authority to issue regulations for the efficient enforcement of the FD&C Act.

The provisions of the proposed rule that would require the electronic submission of labeling are issued under the authority of sections 510(p) and 701(a) of the FD&C Act. Section 510(p) requires that registrations and listings under section 510 be submitted to the Secretary by electronic means unless the Secretary grants a request for waiver because the use of electronic means is not reasonable for the person requesting such waiver.

The failure to include a device in a list required by section 510(j) causes the device to be misbranded under section 502(o) of the FD&C Act. The failure to provide any information required by section 510(j) is a prohibited act under section 301(p) of the FD&C Act.

V. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the proposed rule. We believe that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because annualized costs to small entities are estimated to be less than 0.4 percent of firm revenue, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

B. Summary of Costs and Benefits

This rule proposes to implement provisions of the FD&C Act by requiring firms to electronically submit to FDA the device labels and package inserts, hereafter in this section of the document referred to as ''labeling,'' of certain home-use medical devices. In particular, all devices regulated by CDRH as class II and class III devices and labeled for use in any environment outside a professional health care facility would be covered by this rule. FDA intends to make the labeling of these devices available to the public in a searchable FDA-managed or partner Internet Web site, hereafter referred to in this section of the document as ''labeling database.'' Firms would be required to submit the device labeling to FDA, initially in PDF format but later in SPL format. Firms would incur three types of costs as a result of this rule: Costs to read and understand the rule, costs to reformat labeling according to the rule, and costs to train personnel to comply with the rule. FDA would incur costs to establish and maintain the public online labeling database. The public would benefit from access to information and instructions on the proper use of medical devices in home settings.

The costs and benefits of the proposed rule are summarized in the table 1, entitled ''Economic Data: Costs and Benefits Statement.'' This table shows the estimated average annualized costs and other quantified but not monetized effects of this rule using both 7 and 3 percent annual discount rates over a 10-year evaluation period. We estimate that the present value of costs over 10 years would range from $48.5 to $51.7 million at a 7 percent discount rate and from $52.5 to $56.5 million at a 3 percent discount rate. Annualizing these costs over 10 years yields estimated costs ranging from $6.5 to $6.9 million at a 7 percent discount rate and $6.0 to $6.4 million with a discount rate of 3 percent.

As table 1 shows, the primary benefit stems from a reduced incidence of adverse events due to the increased availability of medical device labeling. We use, as a proxy for those most likely to benefit from this proposed rule, individuals who receive instruction from home health providers on the proper and safe use of their home-use devices. We estimate that the present value number of home-use device training events over 10 years is 66.9 million using a 7 percent discount rate or 80.1 million using a 3 percent discount rate. Annualized over 10 years, we estimate the annual number of home-use device training events is 8.9 million with a 7 percent discount rate and 9.1 million with a 3 percent discount rate. Under the proposed rule, we estimate that for each home-use device training event, the rule would cost between $0.73 and $0.77 using a 7 percent discount rate; with a 3 percent discount rate, the cost per event would range from $0.66 to $0.71.

TABLE 1—ECONOMIC DATA: COSTS AND BENEFITS STATEMENT

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits							
Annualized Monetized $millions/year.	.....	.....	.....	.....	7 3		
Annualized Quantified.	8.9 million home-use device training events.	.....	.....	.....	7	10 years	Reduced incidence of adverse events due to availability of labeling.
	9.1 million home-use device training events.	.....	.....	.....	3	10 years.	
Qualitative							
Costs							
Annualized Monetized $millions/year.	$6.6 million ..... $6.1 million	$6.5 million $6.0 million	$6.9 million $6.4 million	2011 2011	7 3	10 years ..... 10 years	Includes industry costs to read and understand the rule, reformat labeling, and train personnel as well as FDA costs to establish and maintain the labeling database.
Annualized Quantified.	.....	.....	.....	.....	7		
Qualitative	.....	.....	.....	.....	3	.....	
Transfers							
Federal Annualized Monetized $millions/year.	.....	.....	.....	.....	7 3	.....	None.
From/To	From:			To:			
Other Annualized Monetized $millions/year.	.....	.....	.....	.....	7 3	.....	
From/To	From:			To:			
Effects.							
State, Local, or Tribal Government.							
Small Business.							
Annual cost per affected small entity is estimated to be less than 0.4 percent of revenues.							
Wages: No estimated effect.							
Growth: No estimated effect.							

C. Summary of Regulatory Flexibility Analysis

To determine the impact of the proposed rule on small entities, we compare the estimated cost of the rule to the average revenues of the small entities. Assuming that each small firm is composed of a single establishment, the annualized cost to small entities of the proposed rule is not expected to exceed 0.22 percent of firm revenue. The largest impact would be felt by firms with fewer than 100 employees. If instead we assume that each small firm is composed of three establishments, the annualized cost to small entities of the proposed rule is not expected to exceed 0.38 percent of firm revenue. Given that we estimate the cost of the proposed rule to be a very small percentage of firm revenue, the Agency proposes to certify that this proposed rule will not have a significant economic impact on a substantial number of small entities.

The full analysis of economic impacts is available in the docket for this proposed rule (Ref. 12) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses.*

VI. Information Collection Requirements

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section of this document with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices: Submission of Certain Home-Use Device Labels and Package Inserts to FDA

Description: This proposed rule implements statutory directives of section 510(j) of the FD&C Act regarding information required to list a medical device, and amendments enacted in 2002 and 2007 with respect to section 510(p) of the FD&C Act that require all registration and listing information to be submitted ''by electronic means'' (except where FDA grants a waiver from the use of electronic means). The collection requirements associated with this regulation will help ensure that patients, caregivers, and health care professionals have free, timely, and unimpeded access to a trusted source of comprehensive information essential to the safe and effective use of class II and class III home-use devices, even if such devices become separated from their original labeling. We believe that the public will benefit from the improved availability of information, accompanying search tools, and links to other FDA information. Ultimately, it is FDA's hope that access to this information will contribute to improved medical outcomes and a reduction in adverse events.

Specifically, if a home-use device is subject to the proposed rule its label and any package insert would be required to be submitted whenever that device is listed with FDA. Device listing information must be submitted electronically to FDA once each year, during the period from October 1 through December 31. Once a device's labeling has been submitted to FDA, the establishment may thereafter either submit revised labeling with each annual listing of the device to which it pertains, or may certify that no change has been made to the previously submitted labeling. The certification option would simplify the process by not requiring the submission of materials that would duplicate materials previously submitted to FDA. The proposed rule would make clear that the voluntary submission of the label and package insert of a home-use device would be permitted in some circumstances. When finalized, the information collection requirements outlined in this section will amend the current OMB PRA approval for the current Registration and Listing Information collection approved under OMB control number 0910–0625.

Description of Respondents: The likely respondents for this collection of information are domestic device establishments who plan to sell, or who are continuing to sell, their products within the United States.

FDA estimates the burden, on average, of this collection of information as follows:

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section 510(p)/information collection activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Initial Electronic Labeling Submission	2,280	5.4114	12,338	0.25 (15 minutes)	3,084.5
Ongoing Annual Certification of Labeling Submission	2,280	1.0825	2,468	0.25 (15 minutes)	617
Ongoing Annual Electronic Labeling	2,280	6	13,680	0.25 (15 minutes)	3,420
Total					7,121.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**). All comments should be identified with the title ''Medical Devices: Submission of Home-Use Device Labels and Package Inserts to FDA''.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

VII. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Proposed Effective Date

FDA proposes that this rule will go into effect 90 days after publication of a final rule, if that results in an effective date prior to October 1 of the year of publication; otherwise, FDA proposes this rule will go into effect on January 1 of the year following publication of a final rule.

IX. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this proposed rule, if finalized, does not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we

conclude that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. ''Medical Device Home Use Initiative,'' FDA, April 2010, available at *http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/UCM209056.pdf.*
2. ''Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers,'' FDA, April 2001, available at *http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm070782.htm.*
3. ''Medical Instrumentation—Accessibility and Usability Considerations,'' Jack M. Winters and Molly Follette Story, eds., CRC Press, 2007.
4. ''Basic Statistics About Home Care,'' The National Association for Home Care and Hospice 2010, available at *http://www.nahc.org/assets/1/7/10hc_stats.pdf.*
5. ''CDRH Preliminary Internal Evaluations—Volume II: Task Force on the Utilization of Science in Regulatory Decision Making,'' August 2010, p. 10, available at *http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm220783.pdf.*
6. ''CDRH Preliminary Internal Evaluations—Volume I: 510(k) Working Group Preliminary Report and Recommendations,'' FDA, August 2010, pp. 85–86, available at *http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhreports/ucm220784.pdf.*
7. ''510(k) and Science Report Recommendations: Summary and Overview of Comments and Next Steps,'' FDA, January 2011, available at *http://www.fda.gov/downloads/aboutfda/centersoffices/cdrh/cdrhreports/ucm239449.pdf.*
8. Transcript of April 7, 2011, public meeting, ''Medical Device Use in the Home Environment Workshop: Implications for the Safe and Effective Use of Medical Device Technology Migrating into the Home'' (May 24, 2011), available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm215636.htm.*
9. ''Medical Device Labeling for Health Care Practitioners: Focus Group Study,'' RTI International, May 2011, OMB control number 0910–0497, available at *http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/UCM335197.pdf.*
10. ''Device Labeling Study: Practitioner Perspectives on Utility, Format, and Content of an Abbreviated Version of Labeling: Report Summary,'' RTI International, March 2013, OMB control number 0910–0715, available at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/ucm386369.htm.*
11. ''Public Workshop—Medical Device Patient Labeling, September 29–30, 2015'' available at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm455361.htm.*
12. ''Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, and Unfunded Mandates Reform Act Analysis for Electronic Submission of Labeling for Certain Home-Use Medical Devices,'' available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses//default.htm.*

List of Subjects

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 807 be amended as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

■ 1. The authority citation for part 807 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271.

§ 807.26 [Amended]

■ 2. Amend § 807.26(e) introductory text by removing the word ''only''.

§ 807.40 [Amended]

■ 3. Amend § 807.40(a) by removing the words ''subpart B'' and adding in their place ''subparts B and F''.

■ 4. Add subpart F, consisting of §§ 807.200 through 807.300, to read as follows:

Subpart F—Submission of Labeling When Listing Certain Home-Use Devices

Sec.

Subpart F—Submission of Labeling When Listing Certain Home-Use Devices

§ 807.200 Home-use device definitions.

The definitions of this section apply only to this subpart and not for other purpose, including the categorization of in vitro diagnostic products under 42 CFR 493.15:

Home-use device means a medical device that is labeled for use in any environment outside a professional health care facility.

Package insert means all informational materials directed to the user of the device, and which are provided in a device package or which contemporaneously accompany the device when it is delivered to the user, including by electronic means.

§ 807.205 Submission of labeling required for listing certain home-use devices.

Whenever this part requires the owner or operator of an establishment to submit listing information, and the listing concerns a home-use device regulated by the Center for Devices and Radiological Health as a class II or class III medical device, the owner or operator must submit the label and package insert of that home-use device by electronic means in a format specified by FDA that we can process, review, and archive. If a waiver from filing registration and listing information electronically has been obtained under § 807.21(b), the label and package insert shall be submitted in the same manner as other registration and listing information, as directed by § 807.34.

§ 807.220 Voluntary submission of labeling for a home-use device.

(a) If listing a home-use device that is not regulated by the Center for Devices and Radiological Health as a class II or class III medical device, the owner or operator may submit the label and package insert for the device.

(b) If a listing of a home-use device represents more than one product catalog or model number, the owner or operator may submit the label and package insert for each catalog or model number.

(c) An owner or operator may submit the label and package insert for a home-use device that is not currently listed if that device was previously listed pursuant to this part but has been discontinued.

§ 807.300 When updated labeling for a home-use device must be submitted to FDA.

(a) Whenever this part requires updated listing information to be submitted, and the updated listing concerns a home-use device regulated by the Center for Devices and Radiological Health as a class II or class III medical device, the owner or operator shall determine whether any change has been made to the labeling most-recently submitted to FDA for the device. If any change has been made to the most recently submitted labeling, the owner or operator shall submit the current labeling. If no change has been made to the most recently submitted labeling, the owner or operator shall provide a statement to that effect.

(b) The owner or operator may voluntarily submit updated labeling for a listed device at any time prior to the time this part requires such labeling to be submitted.

Dated: October 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–25026 Filed 10–14–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 300

[REG–108792–16]

RIN 1545–BN37

User Fees for Installment Agreements; Hearing Cancellation

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document provides notice of the cancellation of a public hearing on proposed regulation relating to proposed amendments to the regulations that provide user fees for installment agreements.

DATES: The public hearing, originally scheduled for October 19, 2016 at 2:00 p.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Regina Johnson of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration) at (202) 317–6901 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking and notice of public hearing that appeared in the **Federal Register** on Monday, August 22, 2016 (81 FR 56543) announced that a public hearing was scheduled for October 19, 2016 at 2 p.m. in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue NW., Washington, DC. The subject of the public hearing is under section 6159 of the Internal Revenue Code.

The public comment period for these regulations expired on October 6, 2016. The notice of proposed rulemaking and notice of hearing instructed those interested in testifying at the public hearing to submit a request to speak and outline of the topics to be addressed. As of October 6, 2016, no one has requested to speak. Therefore, the public hearing scheduled October 19, 2016 at 2 p.m. is cancelled.

Crystal Pemberton,

Senior Federal Register Liaison, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel.

[FR Doc. 2016–25055 Filed 10–14–16; 8:45 am]

BILLING CODE 4830–01–P

POSTAL SERVICE

39 CFR Part 20

International Mailing Services: Proposed Price Changes

AGENCY: Postal Service™.

ACTION: Proposed rule.

SUMMARY: In October 2016, the Postal Service filed a notice of mailing services price adjustments with the Postal Regulatory Commission (PRC) for products and services covered by *Mailing Standards of the United States Postal* Service, International Mail Manual (IMM®), to be effective on January 22, 2017. The Postal Service will revise Notice 123, *Price List* on *Postal Explorer*® at *http://pe.usps.com* to reflect the new prices.

DATES: We must receive your comments on or before November 16, 2016.

ADDRESSES: Mail or deliver comments to the manager, Product Classification, U.S. Postal Service®, 475 L'Enfant Plaza SW., RM 4446, Washington, DC 20260–5015. You may inspect and photocopy all written comments at USPS® Headquarters Library, 475 L'Enfant Plaza SW., 11th Floor N, Washington, DC by appointment only between the hours of 9 a.m. and 4 p.m., Monday through Friday by calling 1–202–268–2906 in advance. Email comments, containing the name and address of the commenter, may be sent to: *ProductClassification@usps.gov,* with a subject line of ''January 2017 International Mailing Services Price Change.'' Faxed comments are not accepted.

FOR FURTHER INFORMATION CONTACT: Paula Rabkin at 202–268–2537.

SUPPLEMENTARY INFORMATION: The Postal Service hereby gives notice that, pursuant to 39 U.S.C. 3622, on October 12, 2016, it filed with the Postal Regulatory Commission a *Notice of Market-Dominant Price Adjustment.* Proposed prices and other documents relevant to this filing are available under Docket No. R2017–1 on the PRC's Web site at *www.prc.gov.*

This proposed rule includes price changes for certain international extra services.

First-Class Mail International

We propose no increase to prices for single-piece First-Class Mail International® letters, postcards, and flats. The price of a single piece 1-ounce letter is proposed to continue to be $1.15. The First-Class Mail International letter nonmachinable surcharge will not increase.

International Extra Services and Fees

The Postal Service proposes to increase prices for certain market dominant international extra services including:

- Certificate of Mailing (5.36%)
- Registered Mail™ (11.57%)
- Return Receipt (4.1%)
- Customs Clearance and Delivery Fee (4.3%)
- International Business Reply™ Service (average of 2.9%).

Extra Services

CERTIFICATE OF MAILING

Individual pieces	Fee
Individual article (PS Form 3817)	$1.35
Firm mailing books (PS Form 3665), per article listed (minimum 3)	0.39
Duplicate copy of PS Form 3817 or PS Form 3665 (per page)	1.35
Bulk quantities	**Fee**
First 1,000 pieces (or fraction thereof)	$7.95
Each additional 1,000 pieces (or fraction thereof)	0.99
Duplicate copy of PS Form 3606	1.35

Registered Mail

Fee: $14.95.

Return Receipt

Fee: $3.85.