Based on FDA's review of current scientific literature, FDA would not consider the determination of carrier status by detection of clinically relevant gene mutations associated with the diseases and conditions listed in Table 1 to constitute a different intended use from that of a legally marketed device in the generic type 21 CFR 866.5940 for purposes of § 866.9(a). Thus such uses would be 510(k)-exempt once there is compliance with special controls. A gene mutation detection system indicated for the determination of carrier status by detection of clinically relevant gene mutations associated with Cystic Fibrosis is not 510(k)-exempt since it is a class II device subject to premarket notification and special controls under 21 CFR 866.5900—*Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system.*

TABLE 1

Beta Thalassemia
Bloom Syndrome
Canavan Disease
Congenital Disorder of Glycosylation Type 1a (PMM2–CDG)
Autosomal Recessive Connexin 26-Nonsyndromic Hearing Loss
D-Bifunctional Protein Deficiency
Dihydrolipoamide Dehydrogenase Deficiency
Familial Dysautonomia
Familial Mediterranean Fever
Fanconi Anemia Group C
Gaucher Disease
Glycogen Storage Disease Type 1 (1a and 1b)
Gracile Syndrome
Hereditary Fructose Intolerance
Junctional Epidermolysis Bullosa (LAMB3-related)
Leigh Syndrome, French Canadian Type (LSFC)
Autosomal Recessive Limb-girdle Muscular Dystrophy
Maple Syrup Urine Disease
Medium-Chain Acyl-CoA Dehydrogenase (MCAD) Deficiency
Mucolipidosis IV
Autosomal Recessive Neuronal Ceroid Lipofuscinosis (CLN5-related)
Autosomal Recessive Neuronal Ceroid Lipofuscinosis (PPT1-related)
Niemann-Pick Disease—Type A
Nijmegen Breakage Syndrome
Pendred Syndrome
Phenylketonuria
Autosomal Recessive Polycystic Kidney Disease
Primary Hyperoxaluria Type 2 (PH2)
Rhizomelic Chondrodysplasia Punctata Type 1 (RCDP1)
Salla Disease
Sickle Cell Anemia
Sjögren-Larsson Syndrome
Autosomal Recessive Spastic Ataxia of Charlevoix-Saguenay (ARSACS)
Spinal Muscular Atrophy
Tay Sachs Disease
Tyrosinemia Type I
Usher Syndrome Type 1F
Usher Syndrome Type III
Zellweger Syndrome Spectrum

Exemption from the requirement of premarket notification does not exempt a device from other applicable regulatory controls under the FD&C Act, including the applicable general and special controls. Indeed, FDA's decision to propose 510(k) exemption for these devices is based, in part, on the special controls, in combination with general controls, providing sufficiently rigorous mitigations for the risks identified for this generic type.

Subject to the limitations described previously, FDA has determined that the requirement of premarket notification is not necessary to assure the safety and effectiveness of an autosomal recessive carrier screening gene mutation detection system. Accordingly, FDA is announcing its intent to exempt from the premarket notification requirements autosomal recessive carrier screening gene mutation detection systems, subject to the limitations described previously. FDA is publishing this notice in order to obtain comments regarding the proposed exemption.

V. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information 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). The collections of information in 21 CFR part 807, subpart, E have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

VI. Reference

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

1. ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 1998, available at *http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf.*

Dated: October 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27198 Filed 10–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3815]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission of Medical Device Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with electronic submission of medical device registration and listing.

DATES: Submit either electronic or written comments on the collection of information by December 28, 2015.

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–2015–N–3815 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Submission of Medical Device Registration and Listing.'' 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.fda.gov/regulatoryinformation/dockets/default.htm.*

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.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following 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.

Electronic Submission of Medical Device Registration and Listing—21 CFR Part 807, Subparts A Through E; OMB Control Number 0910–0625—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360) and part 807, subparts A through D (21 CFR part 807, subparts A through D), medical device establishment owners and operators are required to electronically submit establishment registration and device listing information.

Complete and accurate registration and listing information is necessary to accomplish a number of statutory and regulatory objectives, such as: (1) Identification of establishments producing marketed medical devices, (2) identification of establishments producing a specific device when that device is in short supply or is needed for national emergency, (3) facilitation of recalls for devices marketed by owners and operators of device establishments, (4) identification and cataloguing of marketed devices, (5) administering postmarketing surveillance programs for devices, (6) identification of devices marketed in violation of the law, (7) identification and control of devices imported into the country from foreign establishments, (8) and scheduling and planning inspections of registered establishments under section 704 of the FD&C Act (21 U.S.C. 374)

Respondents to this information collection are owners or operators of establishments that engage in the manufacturing, preparation, propagation, compounding, or processing of a device or devices, who must register their establishments and submit listing information for each of their devices in commercial distribution. Notwithstanding certain exceptions, foreign device establishments that manufacture, prepare, propagate, compound, or process a device that is imported or offered for import into the United States must also comply with the registration and listing requirements. The number of respondents is based on data from the FDA Unified Registration and Listing System.

Burden estimates are based on recent experience with the existing medical device registration and listing program, electronic system operating experience, and the economic analysis for the final

rule entitled ''Implementation of Device Registration and Listing Requirements Enacted in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Medical Device User Fee and Modernization Act of 2002, and Title II of the Food and Drug Administration Amendments Act of 2007.''

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
807.20(a)(5) [2]—Submittal of manufacturer information by initial importers	3673	8,594	1	8,594	1.75	15,040
807.20(a)(5) [3]—Submittal of manufacturer information by initial importers	3673	8,594	3	25,782	0.1	2,578
807.21(a) [3]—Creation of electronic system account	3673	3,559	1	3,559	0.5	1,780
807.21(b) [2]—Annual request for waiver from electronic registration & listing	.....	14	1	14	1	14
807.21(b) [3]—Initial request for waiver from electronic registration & listing	.....	4	1	4	1	4
807.22(a) [3]—Initial registration & listing	3673	3,539	1	3,539	0.5	1,770
807.22(b)(1) [3]—Annual registration	3673	20,355	1	20,355	0.75	15,266
807.22(b)(2) [3]—Other updates of registration	3673	4,176	1	4,176	0.5	2,088
807.22(b)(3) [3]—Annual update of listing information	3673	19,875	1	19,875	1	19,875
807.26(e) [3]—Labeling & advertisement submitted at FDA request	.....	71	1	71	1	71
807.34(a) [2]—Initial registration & listing when electronic filing waiver granted	.....	14	1	14	1	14
807.34(a) [3]—Annual registration & listing when electronic filing waiver granted	.....	4	1	4	1	4
807.40(b)(2) [3]—Annual update of US agent information	3673	1,615	1	1,615	0.5	808
807.40(b)(3) [3]—US agent responses to FDA requests for information	3673	1,535	1	1,535	0.25	384
807.41(a) [3]—Identification of initial importers by foreign establishments	3673	10,329	1	10,329	0.5	5,165
807.41(b) [3]—Identification of other parties that facilitate import by foreign establishments	3673	10,329	1	10,329	0.5	5,165
Total on-time burden	.....	.....	.....	.....	.....	15,068
Total recurring burden	.....	.....	.....	.....	.....	54,958

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.
[3] Recurring burden.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
807.25(d) [2]—List of Officers, Directors & Partners	23,806	1	23,806	0.25	5,952
807.26 [2]—Labeling & Advertisements Available for Review	11,746	4	46,984	0.5	23,492
Total	.....	.....	.....	.....	29,444

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

Dated: October 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–27199 Filed 10–26–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3517]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Draft Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled ''Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' The draft guidance describes FDA's interim regulatory policy regarding the use of bulk drug substances by licensed pharmacists in State-licensed pharmacies or Federal facilities and by licensed physicians to compound human drug products while FDA develops the list of bulk drug substances that can be used in compounding under the Federal Food, Drug, and Cosmetic Act (FD&C Act). When final, the guidance will reflect the Agency's current thinking on the issues addressed by the guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency