(*2*) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vi) Labeling must also include the following statements, prominently placed:

(A) ''For use only on a single patient. Discard the entire device after use.''

(B) ''Warning: Not intended for more than one use. Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested.''

(b) *Single use only blood lancet without an integral sharps injury prevention feature*—(1) *Identification.* A disposable blood lancet intended for a single use that is comprised of a single use blade attached to a solid, non-reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) *Classification.* Class II (special controls). The special controls are:

(i) The design characteristics of the device must ensure that the structure and material composition are consistent with the intended use and address the risk of sharp object injuries and bloodborne pathogen transmissions;

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use;

(iii) The device must be demonstrated to be biocompatible;

(iv) Sterility testing must demonstrate the sterility of the device;

(v) Labeling must include:

(A) Detailed descriptions, with illustrations, of the proper use of the device.

(B) Handwashing instructions for the user before and after use of the device.

(C) Instructions on cleaning and disinfection of the skin to be pierced.

(D) Instructions for the safe disposal of the device.

(E) Labeling must be appropriate for the intended use environment.

(*1*) For those devices intended for health care settings, labeling must address the health care facility use of these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(*2*) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vi) Labeling must also include the following statements, prominently placed:

(A) ''For use only on a single patient. Discard the entire device after use.''

(B) ''Warning: Not intended for more than one use. Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested.''

(c) *Multiple use blood lancet for single patient use only*—(1) *Identification.* A multiple use capable blood lancet intended for use on a single patient that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) *Classification.* Class II (special controls). The special controls are:

(i) The design characteristics of the device must ensure that:

(A) The lancet blade can be changed with every use, either manually or by triggering a blade storage unit to discard the used blade and reload an unused blade into the reusable base; and

(B) The structure and material composition are consistent with the intended use and address the risk of sharp object injuries and bloodborne pathogen transmissions; and allow for validated cleaning and disinfection;

(ii) Mechanical performance testing must demonstrate that the device will withstand forces encountered during use;

(iii) The device must be demonstrated to be biocompatible;

(iv) Sterility testing must demonstrate the sterility of the device;

(v) Validation testing must demonstrate that the cleaning and disinfection instructions are adequate to ensure that the reusable lancet base can be cleaned and low level disinfected.

(vi) Labeling must include:

(A) Detailed descriptions, with illustrations, of the proper use of the device.

(B) The Environmental Protection Agency (EPA) registered disinfectant's contact time for disinfectant use.

(C) Handwashing instructions for the user before and after use of the device.

(D) Instructions on cleaning and disinfection of the skin to be pierced.

(E) Instructions on the cleaning and disinfection of the device.

(F) Instructions for the safe disposal of the device.

(G) Instructions for use must address the safe storage of the reusable blood lancet base between uses to minimize contamination or damage and the safe storage and disposal of the refill lancet blades.

(H) Labeling must be appropriate for the intended use environment.

(*1*) For those devices intended for health care settings, labeling must address the health care facility use of these devices, including how these lancets are to be used with personal protective equipment, such as gloves.

(*2*) For those devices intended for use in the home, labeling must be written so that it is understandable to lay users.

(vii) Labeling must also include the following statements, prominently placed:

(A) ''For use only on a single patient. Disinfect reusable components according to manufacturer's instructions between each use.''

(B) ''Used lancet blades must be safely discarded after a single use.''

(C) ''Warning: Do not use on more than one patient. Improper use of blood lancets can increase the risk of inadvertent transmission of bloodborne pathogens, particularly in settings where multiple patients are tested. The cleaning and disinfection instructions for this device are intended only to reduce the risk of local use site infection; they cannot render this device safe for use for more than one patient.''

(d) *Multiple use blood lancet for multiple patient use*—(1) *Identification.* A multiple use capable blood lancet intended for use on multiple patients that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

(2) *Classification.* Class III (premarket approval).

Dated: February 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04578 Filed 3–2–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2016–M–0035]

Effective Date of Requirement for Premarket Approval for Blood Lancets

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed administrative order to require the filing of a premarket approval application (PMA) following the reclassification of multiple use blood lancets for multiple patient use from class I to class III. FDA is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring this device to meet the PMA requirements of the Federal Food, Drug,

and Cosmetic Act (the FD&C Act) and the benefits to the public from the use of the device.

DATES: Submit either electronic or written comments on this proposed order by June 1, 2016. See section X of the **SUPPLEMENTARY INFORMATION** section of this document for the proposed effective date of any final order that may publish based on this proposal.

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–M–0035 for ''Effective Date of Requirement for Premarket Approval for Blood Lancets.'' 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: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G422, Silver Spring, MD 20993–0002, 301–796–6524, *joshua.nipper@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The FD&C Act, as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d)(1) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as ''preamendments devices''), are classified after FDA: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as ''postamendments devices''), are classified automatically by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, FDA reclassifies the device into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A person may market a preamendments device that has been classified into class III through premarket notification procedures, and devices found substantially equivalent by means of premarket notification (510(k)) procedures to such a preamendments device or to a device within that type (both the preamendments and substantially equivalent devices are referred to as preamendments class III devices) may be marketed without submission of a PMA until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval. Section 515(b)(1) of the FD&C Act directs FDA to issue an order requiring premarket approval for a preamendments class III device.

Section 515(f) of the FD&C Act provides an alternative pathway for meeting the premarket approval

requirement. Under section 515(f), manufacturers may meet the premarket approval requirement if they file a notice of completion of a product development protocol (PDP) approved under section 515(f)(4) of the FD&C Act and FDA declares the PDP completed under section 515(f)(6)(B) of the FD&C Act. Accordingly, the manufacturer of a class III preamendments device may comply with a call for PMAs by filing a PMA or a notice of completion of a PDP. In practice, however, the option of filing a notice of completion of a PDP has rarely been used. For simplicity, although the PDP option remains available to manufacturers in response to a final order under section 515(b) of the FD&C Act, this document will refer only to the requirement for the filing and obtaining approval of a PMA.

On July 9, 2012, Congress enacted the Food and Drug Administration Safety and Innovation Act (FDASIA). Section 608(b) of FDASIA (126 Stat. 1056) amended section 515(b) of the FD&C Act, changing the process for requiring premarket approval for a preamendments class III device from rulemaking to an administrative order.

Section 515(b)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order requiring premarket approval for a preamendments class III device, the following must occur: Publication of a proposed order in the **Federal Register**, a meeting of a device classification panel described in section 513(b) of the FD&C Act, and consideration of comments to a public docket.

In June 2013, FDA held a meeting of a device classification panel described in section 513(b) of the FD&C Act to discuss the classification of multiple use blood lancets for multiple patient use. Although, to FDA's knowledge, no device is currently being marketed for this use, one device has been cleared for this use. As explained further in section V.A of this document, this device classification panel meeting discussed whether multiple use blood lancets for multiple patient use should be reclassified into class III or remain in class I, and the discussion included whether PMAs should be required for these devices. The panel recommended that, because multiple use blood lancets for multiple patient use present a potential unreasonable risk of illness or injury and insufficient information exists to establish special controls for multiple use blood lancets for multiple patient use, the device should be reclassified into class III. FDA is not aware of new information that would provide a basis for a different recommendation or findings.

Section 515(b)(2) of the FD&C Act provides that a proposed order to require premarket approval shall contain: (1) The proposed order, (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA and the benefit to the public from the use of the device, (3) an opportunity for the submission of comments on the proposed order and the proposed findings, and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(3) of the FD&C Act provides that FDA shall, after the close of the comment period on the proposed order, consideration of any comments received, and a meeting of a device classification panel described in section 513(b) of the FD&C Act, issue a final order to require premarket approval or publish a document terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the FD&C Act, unless the reason for termination is that the device is a banned device under section 516 of the FD&C Act (21 U.S.C. 360f).

A preamendments class III device may be commercially distributed without a PMA until 90 days after FDA issues a final order requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the FD&C Act becomes effective, whichever is later (section 501(f) of the FD&C Act (21 U.S.C. 351(f)). Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed order to reclassify multiple use blood lancets for multiple patient use from class I to class III. Therefore, assuming both the reclassification order and the order to require PMAs are finalized at the same time, the date by which a PMA for multiple use blood lancets for multiple patient use must be filed will be 30 months after the date FDA issues the final order reclassifying multiple use blood lancets for multiple patients. If a PMA is not filed for such device by the later of the two dates, as specified in section 501(f)(2)(B) of the FD&C Act, then the device would be deemed adulterated under section 501(f) of the FD&C Act unless the device is distributed for investigational use under an approved application for an investigational device exemption (IDE).

In accordance with section 515(b) of the FD&C Act, interested persons are being offered the opportunity to request reclassification of multiple use blood lancets for multiple patient use.

II. Regulatory History of the Device

Elsewhere in this issue of the **Federal Register**, FDA is proposing to reclassify multiple use blood lancets for multiple patient use into class III under section 513(e) of the FD&C Act.

Blood lancets were classified in part 878 (21 CFR part 878) by a final rule published in the **Federal Register** on June 24, 1988 (53 FR 23856) that classified 51 general and plastic surgery devices. This 1988 rule classified blood lancets into class I (general controls). These devices were grouped with other devices under ''Manual surgical instrument for general use,'' 21 CFR 878.4800. At the time, blood lancets had been in common use in medical practice for many years, and FDA believed that general controls were sufficient to provide reasonable assurance of the safety and effectiveness of those devices. This rule was amended on April 5, 1989 (54 FR 13826) to clarify that manual surgical instruments for general use made of the same materials as used in preamendment devices were exempt from premarket notification 510(k) review.

On December 7, 1994, FDA further amended the classification when it published a final rule in the **Federal Register** (59 FR 63005) that exempted 148 class I devices from premarket notification, with limitations. Blood lancets were one of those devices. FDA determined that manufacturers' submissions of premarket notifications were unnecessary for the protection of the public health and that FDA's review of such submissions would not advance its public health mission.

On August 26, 2010, FDA and the Centers for Disease Control and Prevention (CDC) issued joint initial communications warning that the use of fingerstick devices (blood lancets) to obtain blood from more than one patient posed a risk of transmitting bloodborne pathogens. The communication was updated on November 29, 2010 (Ref. 1). FDA's communication update, ''Use of Fingerstick Devices on More Than One Person Poses Risk for Transmitting Bloodborne Pathogens: Initial Communication: Update 11/29/2010'', stated that ''[o]ver the past 10–15 years, the CDC and the FDA have noted a progressive increase in reports of bloodborne infection transmission (primarily hepatitis B virus) resulting from the shared use of fingerstick and POC [or 'Point of Care'] blood testing devices.'' FDA and CDC recommended, among other things, that health care

professionals and patients never use a blood lancet for more than one person.

On November 29, 2010, FDA published a guidance entitled ''Guidance for Industry and Food and Drug Administration Staff; Blood Lancet Labeling'' (75 FR 73107) (Ref. 2). This guidance includes labeling recommendations to address concerns that both health care providers and patients may be unaware of the serious adverse health risks associated with using the same blood lancet for assisted withdrawal of blood from more than one patient, even when the blood lancet blade is changed for each blood draw. FDA recommends in the guidance that all blood lancets be labeled for use only on a single patient. FDA recommends in the guidance that a statement limiting use to a single patient should also appear on the label attached to the device, if possible. The guidance was for immediate implementation. When final, this order will supersede this labeling guidance.

On June 26, 2013, FDA held a meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee (the Panel) to discuss the potential reclassification of blood lancets (Ref. 3). The Panel discussed new scientific information, the risks to health from blood lancets, whether blood lancets should be reclassified or remain in class I, and possible special controls for these devices if reclassified into class II. The Panel agreed that general controls were not sufficient to provide a reasonable assurance of safety and effectiveness of blood lancets. The Panel believed that because multiple use blood lancets for multiple patient use presented a potential unreasonable risk of illness or injury, and insufficient information existed to establish special controls for these devices, they should be reclassified into class III. The Panel recommended that all other blood lancet devices be reclassified into class II (special controls). FDA is not aware of new information since this Panel meeting that would provide a basis for a different recommendation or finding.

III. Dates New Requirements Apply

Assuming FDA finalizes the order proposing reclassification of multiple use blood lancets for multiple patient use found elsewhere in this issue of the **Federal Register**, this device will be classified into class III. In accordance with sections 501(f)(2)(B) and 515(b) of the FD&C Act, FDA is proposing to require that a PMA be filed with the Agency for multiple use blood lancets for multiple patient use devices and accessories by the last day of the 30th calendar month beginning after the month in which the classification of the device in class III became effective, or on the 90th day after the date of the issuance of a final order under 515(b), whichever is later. Assuming this order is finalized at or near the same time the final order to reclassify these devices into class III, this requirement will take effect 30 months after the reclassification order issues. An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found to be substantially equivalent to such a device, will be permitted to continue marketing such class III devices during FDA's review of the PMA provided that a PMA is timely filed. FDA intends to review any PMA for the device within 180 days. FDA cautions that under section 515(d)(1)(B)(i) of the FD&C Act, the Agency may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the Agency finds that ''. . . the continued availability of the device is necessary for the public health.''

Under the FD&C Act, if any multiple use blood lancets for multiple patient use are currently in distribution and no PMA is submitted for these devices by the last day of the 30th calendar month beginning after the month in which the classification of the device in class III became effective or within 90 days of a final order calling for PMAs, or a denial is rendered on a filed PMA, these devices would be considered adulterated under section 501(f)(1) of the FD&C Act. In addition, no new devices will be permitted in interstate commerce without approval of a PMA. The device may be distributed for investigational use only if the requirements of the IDE regulations are met. The requirements for significant risk devices include submitting an IDE application to FDA for review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued under § 812.30 (21 CFR 812.30). FDA, therefore, recommends that IDE applications be submitted to FDA at least 30 days before the end of the 30-month period after the issuance of the final order to avoid interrupting any ongoing investigations.

FDA intends that under § 812.2(d), the publication in the **Federal Register** of any final order based on this proposal will include a statement that, as of the date on which the filing of a PMA is required, the exemptions in § 812.2(c)(1) and (2) from the requirements of the IDE regulations for preamendments class III devices will cease to apply to any device that is: (1) Not legally on the market on or before that date, or (2) legally on the market on or before that date but for which a PMA is not filed by that date, or for which PMA approval has been denied or withdrawn.

IV. Device Subject to This Proposal

Multiple Use Blood Lancet for Multiple Patient Use (21 CFR 878.4850(d))

Elsewhere in this issue of the **Federal Register**, FDA is proposing to identify multiple use blood lancet for multiple patient use in a new 21 CFR 878.4850(d) in the following way: A multiple use capable blood lancet intended for use on multiple patients that is comprised of a single use blade attached to a solid, reusable base that is used to puncture the skin to obtain a drop of blood for diagnostic purposes.

V. Proposed Findings With Respect to Risks and Benefits Multiple Use Blood Lancet for Multiple Patient Use

As required by section 515(b) of the FD&C Act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that this device have an approved PMA, and (2) the benefits to the public from the use of the device.

These findings are based on the reports and recommendations of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee (the Panel) from the meeting on June 26, 2013 (Ref. 3) and any additional information that FDA has obtained. Additional information regarding the risks as well as classification associated with this device type can be found in section V.C as well as in the proposed order published elsewhere in this issue of the **Federal Register** proposing to reclassify these devices into class III. The device has the potential to benefit the public by puncturing the skin to obtain small blood specimens for testing blood glucose, hemoglobin, and other blood components. In addition, acute care hospitals may consider reusing a single device or using one device with multiple blades to have benefits in that doing so may expedite procedures. The risks associated with the device include bloodborne pathogen transmission, sharp object injuries, local tissue infections, and adverse tissue reaction (not infection).

A. Summary of Data

FDA uses the bloodborne pathogens definition in 29 CFR 1910.1030(b). Bloodborne pathogens, such as HBV, may be transmitted between patients by blood and certain body fluids (Ref. 4).

Since HBV-infected patients, who often lack clinical symptoms of hepatitis, have high concentrations of HBV in their blood and HBV is stable at ambient temperatures, transmission of HBV may result from exposure to equipment that has not been adequately disinfected or by the misuse of ''single use only'' medical devices (*e.g.,* needles and syringes) (Ref. 5).

The history of recognized bloodborne pathogen transmission by blood lancets may have started in 1923 when an outbreak of jaundice occurred in the Goteborg Hospital diabetic clinic in Sweden, which was described by Schmid et al. (Ref. 6). All patients had blood drawn for glucose testing from their ear lobes by a spring-activated ''Schnepper'' device, which was cleaned ''perfunctorily'' between uses. As a result, 26 clinic patients developed jaundice. Outbreaks of hepatitis in English diabetic patients were described by Graham in 1938 (Ref. 7) and by Droller in 1945 (Ref. 8). In both of these outbreaks, venous blood for glucose measurement was drawn using syringes that were only chemically disinfected between uses while the needles were boiled; cleaning procedures were not mentioned in the reports. Syringes and needles are now single-use-only devices because the procedures used to reprocess these devices many years ago have long been recognized to be inadequate, resulting in outbreaks of hepatitis transmission (Ref. 6). There were also two case reports, in 1985 and 1997, of the transmission of HBV infection due to sharing personal use blood lancets for home glucose monitoring with one other person who already had HBV. One report was from the United States and one was from Hungary (Refs. 9 and 10). In addition, Mendez et al. reported a 75-year-old patient with diabetes who died of acute hepatitis, whose only risk factor for HBV infection appeared to be her diabetic care at a local outpatient facility where she had repeated fingersticks for blood glucose monitoring (Ref. 11).

During the 1990s, several bloodborne transmission issues led to CDC and FDA involvement. In 1990, CDC learned of a nosocomial outbreak of HBV transmission due to the use of a spring-loaded lancet device whose disposable platform was not removed and discarded after each use of the device while it was used for the care of multiple patients (Ref. 12).[1] CDC reported this outbreak to FDA; FDA then issued a safety alert warning users of the precautions needed for the safe use of this device (Ref. 13). This was the first reported outbreak of HBV transmission associated with the use of a blood lancet device in the United States (Refs. 13 and 14).

CDC's outbreak investigation revealed that a patient who had diabetes and also a chronic HBV infection caused by a relatively rare viral subtype was admitted to the outbreak ward in 1989. Twelve of the 23 patients who acquired hepatitis B after admission to the same ward as the chronic HBV source patient were serotyped, and all were found to have the same viral subtype causing their hepatitis B infections. The first nosocomially infected patient had a very long-term stay on the ward and so served as a source of transmission to other patients over a period of 12 months. Twenty of the 23 outbreak patients had diabetes; they and the three other case-patients all experienced numerous POC fingerstick blood draws with the same type of blood lancet while hospitalized on the outbreak ward. The implicated blood lancet device included a disposable platform to stabilize the patient's finger; the single use lancet blade penetrated a hole in that platform to reach the patient's skin. Half the ward nursing staff who performed fingersticks with this lancet acknowledged not changing the device platform with each use of the lancet. A similar outbreak of hepatitis transmission was reported in 1990 in France in which a similar blood lancet device was implicated. Douvin et al. (Ref. 15) reported that examination of the device implicated in the French outbreak showed visible blood contamination of the lancet platform in 24 percent of studied uses of that device. Shier et al. (Ref. 16) reported in 1993 that the use of another spring-loaded lancet device in a volunteer study of blood glucose levels resulted in visible blood contamination on 29 percent of the device end caps. This device was intended for ''personal'' use only.

As a result of the 1990 outbreak of HBV transmission due to blood lancet use in the United States, FDA and CDC recommended that spring-loaded blood lancet devices should have only single use only ''platforms'' as well as single use only blades; the devices were to be cleaned and disinfected per the manufacturer's instructions (Refs. 12 and 13). The 1990 FDA Safety Alert also advised ''Devices (blood lancets) without a removable platform should only be used with one patient in the hospital or outpatient setting. After the patient is discharged, the device may be reused only if it is disinfected according to the manufacturer's instructions. If there are no instructions for disinfection, the device should be discarded.''

Since 1990, the incidence of diabetes mellitus has increased significantly in the United States, especially in adults aged 65–79 (Refs. 17 and 18). At the same time, clinical practice in the care of these patients increasingly emphasized the need for improved blood glucose level control, resulting in the increased use of POC blood glucose monitoring both in health care facilities and at home (Refs. 19–21). Unfortunately, along with the increased incidence of diabetes has come a progressive increase in the reports of bloodborne infection transmission (primarily HBV), resulting from the shared use of fingerstick and POC blood testing devices (Ref. 1). In 2011, the CDC reported that 25 of 29 outbreaks of HBV infection occurring in long-term care facilities since 1996 involved adults with diabetes receiving blood glucose monitoring (Ref. 22).

In 1997, CDC reported two outbreaks of HBV transmission, one in a nursing home in Ohio and one in a hospital in New York City (NYC) (Ref. 23). Two different blood lancet devices were used at the two sites. However, both lancet devices included the use of an ''end cap'' that came in contact with patient skin. This was a separate, individual use component of the lancet device used in Ohio; the nursing home was reusing both the lancet and the cap for multiple patients. The end cap was a part of the disposable, single use only lancet blade assembly in the device used in NYC. The exact mechanism of blood transmission was not entirely clear in the NYC setting; staff claimed they had discarded the end cap after each use. CDC postulated that either blood-contaminated nurses gloves worn for the care of multiple patients or the pen-like lancet-holding device itself might have been the source of the blood cross-contamination of the lancet. A similar outbreak was reported by Quale et al. in 1998 from a hospital in New York (Ref. 24). The recognition of 3 cases of nosocomially acquired HBV infection resulted in an investigation that uncovered another 11 cases. Reuse by hospital staff of a disposable lancet end cap with the lancet in multiple patients was identified as the probable cause of hepatitis cross-transmission to patients; contamination of the lancet wound from

[1] Hepatitis B and hepatitis C infections, as well as other bloodborne infections such as HIV infection, are reported to State health departments and, by them, to CDC; FDA does not usually receive such reports directly from health care facilities or personnel, even when a medical device has transmitted the infection.

blood on unchanged gloves worn by nurses during collection of blood samples from multiple patients may also have contributed to the nosocomial transmission of HBV in this outbreak.

CDC reviewed the incidence of reported outbreaks of HBV and hepatitis C infection in nonhospital health care settings between 1998 and 2008 and noted a significant increase in such nosocomial transmission of bloodborne pathogens (Refs. 25–28). N.D. Thompson et al. identified 33 outbreaks of nosocomial hepatitis transmission in nonhospital health care settings (Ref. 25). Of these 33 outbreaks, 15 were found to be due to blood glucose monitoring in long-term care and assisted living facilities. Only half of these outbreak investigations were published in the scientific literature; the others were recognized by health department investigations and reports to CDC. In 9 of the 15 outbreaks of nosocomial hepatitis in patients with diabetes, blood lancet devices were shared among multiple patients. In two additional outbreaks, lancets were not noted to be shared, but blood-soiled glucose meters were stored together with lancets without cleaning/disinfection of the devices and gloves were not regularly changed between each patient. These failures of proper infection control practice could have led to blood contamination of individual blood lancets in these two facilities.

N.D. Thompson et al. also investigated blood glucose monitoring practices in long-term care facilities in Pinellas County, Florida, in 2007 and found that 22 percent of the participating facilities that used reusable fingerstick devices used them in multiple patients (Ref. 29). Patel et al. reported in 2009 on the efforts of the Virginia Department of Health to improve blood glucose monitoring practices in assisted living facilities (ALFs) in Virginia (Ref. 30). This effort followed two separate outbreaks of HBV infections in two assisted living facilities. In those outbreaks, one of the three acutely symptomatic initial patients died of HBV infection. Of 68 patients undergoing blood glucose monitoring in these two facilities, a total of 11 patients acquired HBV infection. Both facilities used reusable blood lancets to obtain blood from multiple patients and did not clean or disinfect the lancets between uses. The Virginia Department of Health then mailed an educational packet on safe blood glucose monitoring practices to all ALFs (640) in the State. A random sample of ALFs was contacted after the educational intervention and invited to participate in a survey to evaluate the response to the educational packet. The results found that 16 percent of the facilities that used lancets to monitor blood glucose levels were still using these devices to obtain blood from multiple patients.

Y.G. McIntosh et al. investigated outbreaks of nosocomial HBV transmission in four ALFs between 2009 and 2011 and found that in all four facilities, pen-style lancets were used to obtain blood for glucose monitoring from multiple patients even though two facilities provided each patient with dedicated ''single patient use only pen-style lancets'' according to their policies (Ref. 31). Z. Moore et al. reported another outbreak of nosocomial HBV transmission in an ALF in NC in 2010 in which blood lancet devices were shared among multiple patients. Six of the eight elderly patients who acquired acute HBV in this outbreak died from complications of hepatitis (Ref. 32). M.K. Schaefer et al. surveyed a stratified, random sample of ambulatory surgery centers (ACS) in three volunteer states in 2009 (Ref. 33). Of the 53 ACS that performed blood glucose monitoring, 11 (21 percent) reused pen-style blood lancets on multiple patients and 17 (32 percent) also failed to clean and disinfect blood glucose meters after each use.

Thompson and Schaefer reported the analysis of four outbreaks of nosocomial HBV in ALFs in 2009–2010 (Ref. 34). One was also reported separately by Z. Moore et al. (Ref. 32). Two of the three other outbreaks occurred in Virginia and one in Florida; these 3 outbreaks resulted in 21 new patients acquiring acute hepatitis B. In two of the three facilities, use of reusable blood lancets to draw blood from multiple patients was observed or reported. The third facility denied that it permitted the sharing of reusable lancets. However, used lancets and glucose meters were stored together, along with clean supplies; visible blood contamination was observed on several glucose meters and one reusable lancet by the investigator. Thompson and Schaefer also reported in their paper on two patient notification campaigns resulting from the misuse of reusable blood lancets with preloaded lancet cartridges, intended and cleared only for single patient use, which were used to obtain blood from multiple patients. One episode involved a community health center and was reported when personnel noted that the lancet blades were not retracting properly, which might have resulted in blade use for more than one patient. The second episode occurred at a community health fair in which physician assistant students were offering diabetes screening. During the fair, the students realized that the lancet blades had not been advanced properly so that each patient received a new blade. The first episode exposed 283 patients to a contaminated lancet blade; the second incident exposed approximately 60 patients. The results of the patient notification studies were not reported.

As a result of this significant increase in such nosocomial transmission of bloodborne pathogens, on August 26, 2010, FDA and the CDC issued a Safety Communication (Ref. 1) and a Clinical Reminder (Ref. 35), respectively, warning that the use of blood lancets to obtain blood from more than one patient risks the transmission of bloodborne pathogen infections from one patient to other patients. Both FDA and CDC recommended that blood lancets should never be used to obtain blood from more than one patient. In addition, the Centers for Medicare and Medicaid Services issued a Survey and Certification Memorandum for Point of Care Devices and Infection Control in Nursing Homes identifying the use of blood lancet devices for more than one patient as an infection control standards deficiency (Ref. 36). On November 29, 2010, FDA issued ''Guidance for Industry and Food and Drug Administration Staff: Blood Lancet Labeling'', which provided guidance for lancet manufacturers on the labeling of all blood lancets, including those capable of reuse, as ''single patient use only'' devices (Ref. 2).

In 2012, another outbreak of acute HBV was reported in an ALF in Virginia (Ref. 37). The source patient had been recently transferred from another ALF where she had acquired nosocomial HBV infection from the shared use of blood lancets for multiple patients (Ref. 31). This ALF also reused blood lancets to obtain blood from multiple patients for glucose monitoring. This dangerous practice resulted in two new nosocomial HBV infections in this ALF.

Outbreaks of hepatitis transmission due to use of blood lancets to draw blood from more than one patient for blood glucose monitoring have not been limited to the United States. In 2001, Desenclos et al. described an outbreak of nosocomial hepatitis C transmission in an inpatient ward for children with cystic fibrosis and diabetes in a French hospital in 1994–1995 (Ref. 38). Blood glucose monitoring was done by the nursing staff for the patients with cystic fibrosis as well as for the patients with diabetes using a spring-loaded lancet with a disposable platform to stabilize the finger. These devices were shared among patients between 1986 and 1992

during repeated admissions to the inpatient unit. After 1992, patients were supposed to use only their own lancet devices for blood glucose monitoring. The retrospective prevalence of prior hepatitis C infection was found to be 58 percent in patients with cystic fibrosis and 17 percent in patients with diabetes in 1994. At the time (1994), the prevalence of antibody to hepatitis C in the general public in France was 1.1 percent. The patients with cystic fibrosis had more frequent and longer admissions to the inpatient ward, and more of the exposed cystic fibrosis patients (66.7 percent) were screened for hepatitis C infection than were the patients with diabetes admitted to the inpatient ward during the exposure period (39.5 percent). These factors may have influenced the apparent difference in hepatitis C transmission in these two groups of exposed patients.

In 2005, De Schrijver et al. described an outbreak of acute HBV infection in a nursing home in Antwerp (Ref. 39). The initial report of a fulminant case of acute HBV infection in an 83-year-old resident of the home resulted in an investigation that identified acute hepatitis B infection in another four patients there. Four of the five acutely infected patients had diabetes and received assisted blood glucose sampling by the nursing home staff. The two blood lancet models used in the facility (one each in two sections) were used to obtain blood from multiple patients. The device platforms were not disposable. The lancets were washed only when blood was visible on the device and were not disinfected. Nurses did not routinely wash their hands or wear gloves when obtaining blood. Two of the five patients with acute nosocomial hepatitis B died of their infections.

In 2008, Gotz et al. reported the investigation of two cases of acute HBV infection among patients at a nursing home in the Netherlands (Ref. 40). The nursing home stay of these two patients overlapped with that of a patient with known chronic HBV infection. Early in this time period, the nursing home changed the lancet device used for glucose monitoring from a spring-loaded device with a disposable platform (used for multiple patients) to a device with a rotating drum dispensing new lancet blades, which was also used to draw blood from multiple patients, although it was labeled for single patient use only. This device was used for about a month until the staff realized that active rotation of the drum was occasionally forgotten, resulting in the reuse of a lancet blade on more than 1 patient. The new device was then removed from the facility and the spring-loaded lancet was returned to use. The two patients with acute HBV received blood glucose monitoring as did the source patient with chronic HBV, sometimes on the same day. Two other patients who also received blood glucose monitoring escaped infection. The investigators stated that they believed the rotating lancet drum device was likely the means of transmission of HBV infection between patients.

In 2011, Duffell et al. reported on the investigations of five reports of HBV transmission in community health care settings in the United Kingdom (Ref. 4). All of the nine initially reported patients with HBV had diabetes and were receiving blood glucose monitoring. Further investigation identified another 12 patients with acute HBV infection. The care settings in which hepatitis transmission occurred were described as a ''private residential home'' (1 patient), nursing and residential home (1 patient), ''private nursing and residential'' (1 patient) and ''local care home'' (2 patients). Eleven of the 21 acutely infected patients had symptomatic HBV; seven of these patients died, five due to the HBV infection. All of the care sites in which acute HBV transmission occurred were using blood lancets designed intended for single patient use only; these devices were either routinely or occasionally used for multiple patients. One facility also used a single glucometer for multiple patients and did not clean or disinfect it between patients. The authors also noted that information reported on patients found to have acute HBV infection between 1990 and 2003 identified only four patients with blood glucose monitoring as a possible risk factor; one of these patients was infected as a result of in-hospital transmission from another patient on the same ward, although details were not provided. Between 2004 and 2006, the 9 patients described previously in this document were reported and investigation led to the discovery of an additional 12 cases of health care-related HBV transmission due to the improper use of blood lancets during patient blood glucose monitoring.

B. Benefits of the Device

A blood lancet is used to puncture the skin to obtain small blood specimens for testing blood glucose, hemoglobin, and other blood components. Some blood lancets are used with POC blood testing devices, such as blood glucose meters and Prothrombin Time and International Normalized Ratio (PT/INR) anticoagulation meters. Today, probably the most common use for a blood lancet is in diabetes monitoring. These devices are used in both home and professional health care settings. Only a small blood sample is needed for testing of blood glucose level. The blood sample is dropped onto a test strip and inserted into a blood glucose meter for results.

Some blood lancets are also used with PT/INR anticoagulation meters. These devices are used in both home and professional health care settings. The PT and INR are used to monitor the effectiveness of the anticoagulant warfarin. Warfarin helps inhibit the formation of blood clots. The formation of blood clots may be associated with atrial fibrillation, the presence of artificial heart valves, deep venous thrombosis, and some cases of pulmonary embolism. Because the use of warfarin may cause excessive bleeding, patients are monitored, typically by PT/INR.

Because newborns have relatively small amounts of blood compared to adults, it is usually preferred to use as small amount of blood as possible for any screening or other laboratory tests for newborns. Blood lancets may be used to perform heel sticks in newborns. Heel stick is a minimally invasive way of obtaining capillary blood samples. In newborns, heel sticks are the preferred collection method for small volumes of blood.

The possible benefit of multiple use blood lancets for multiple patient use is that acute care hospitals may consider reusing a single device or using one device with multiple blades to have benefits, in that doing so may expedite procedures.

C. Risks to Health

FDA has evaluated the risks to health associated with use of multiple use blood lancets for multiple patient use. In doing so, FDA considered information from the reports and recommendations of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee from the meeting of June 26, 2013, the adverse event reports for these devices in FDA's Manufacturer and User Facility Device Experience (MAUDE) database, and the published scientific literature, which is discussed in FDA's executive summary for the June 26, 2013, panel. Based on this information, FDA has determined the following risks:

1. Bloodborne Pathogen Transmission

Bloodborne pathogens such as HBV, hepatitis C virus, and potentially any other pathogen present in the bloodstream of a patient can be

transmitted from one patient to another by the following mechanisms:

- Reuse of the same lancet blade to draw blood from more than one patient or
- Failure/inability to adequately clean the base of a multiple use blood lancet resulting in the blood contamination of the next ''new'' lancet blade when blood is drawn from more than one patient.

2. Sharp Object Injuries

The blade of a lancet device is designed to pierce the skin and draw blood. Except when the used lancet blade is immediately and automatically covered by a sharps safety feature, which renders the blade inaccessible, the exposed sharp blade of a blood lancet presents a puncture hazard to anyone coming in contact with it. Blade exposure can result due to either the lack of a sharps safety feature or device breakage.

3. Local Tissue Infections

Human skin always carries a population of bacteria and often fungi (normal skin flora), which causes no problem for the host when skin is intact. However, puncture injuries to the skin by sharp objects such as lancet blades can carry these microbes into the normally sterile tissue below the skin. Such injuries have the potential to cause local skin/soft tissue infections.

4. Adverse Tissue Reaction (Not Infection)

Skin contact with some materials, metals and material colorants can cause skin inflammation, irritation or exanthems (rashes). These reactions may be due to either hypersensitivity to a specific compound/metal or to a non-specific reaction.

D. Summary of FDA Findings

FDA believes multiple use blood lancets for multiple patient use should be reclassified from class I to class III. The Panel held on June 26, 2013, discussed and made recommendations regarding the regulatory classification of blood lancets to reclassify multiple use blood lancets for multiple patient use to class III under 513(e) of the FD&C Act. The Panel strongly agreed with FDA that based on the available scientific evidence, multiple use blood lancets for multiple patient use should be reclassified to class III because multiple use blood lancets for multiple patient use present a potential unreasonable risk of illness or injury. They also agreed that insufficient information exists to establish special controls for multiple use blood lancets for multiple patient use, because there is no evidence that these devices can be adequately cleaned and disinfected and that there is no proven method of doing so. Therefore, it is appropriate to regulate them in class III.

FDA agrees with the Panel's recommendation that these devices present a potential unreasonable risk of illness or injury due to the inherent and significantly increased risk of bloodborne pathogen transmission risk as compared to single use only or single patient only blood lancets. FDA does not believe existing valid scientific evidence, as defined in § 860.7 (21 CFR 860.7), supports a reasonable assurance that the device can be adequately reprocessed between uses on different patients. FDA also believes sufficient information does not exist to establish special controls for blood lancets intended for multiple patient use. Given the availability of safer single patient use blood lancet devices, FDA further believes that the probable benefits to health from use of the device do not outweigh the probable risks. Currently FDA is unaware of technology or other controls that would adequately mitigate against the inherent and significantly increased risk of blood borne pathogen transmission in multiple use blood lancets for use in multiple patients. Therefore, the safety and effectiveness of the multiple use blood lancets for multiple patients, particularly the effectiveness of their reprocessing instructions/methods to render the device safe for use on more than one patient and the ability of health care providers to follow these instructions completely should be independently demonstrated for each device of this type via a PMA application. FDA is proposing to require an individual demonstration that a reasonable assurance of safety and effectiveness exists for each device within this type. The manufacturer of each individual device will have the opportunity to demonstrate the safety and effectiveness of the device for its intended use by submitting a PMA.

VI. PMA Requirements

A PMA for this device must include the information required by section 515(c)(1) of the FD&C Act. Such a PMA should also include a detailed discussion of the risks identified previously in this document, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on: (1) Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA must include valid scientific evidence to demonstrate reasonable assurance of the safety and effectiveness of the device for its intended use (§ 860.7(c)(2)). FDA defines valid scientific evidence in § 860.7(c)(2)).

To present reasonable assurance of safety and effectiveness of multiple use blood lancets for multiple patient use, FDA believes manufacturers should submit performance testing, including clinical trials of their device, in order to support PMA approval. Existing published clinical literature may also be leveraged as part of the PMA submission.

VII. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA, FDA is required by section 515(b)(2)(D) of the FD&C Act to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to the classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the FD&C Act.

A request for a change in the classification of this device is to be in the form of a reclassification petition containing the information required by 21 CFR 860.123, including new information relevant to the classification of the device.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) 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.

IX. Paperwork Reduction Act of 1995

This proposed order refers to collections of information 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). The collections of information in 21 CFR part 814, subparts B and E, have been approved under OMB control number 0910–0231. The collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120. The collections of information under 21

CFR part 801 have been approved under OMB control number 0910–0485.

X. Proposed Effective Date

FDA is proposing that any final order based on this proposal become effective on the date of its publication in the **Federal Register** or at a later date if stated in the final order.

XI. Codification of Orders

Prior to the amendments by FDASIA, section 515(b) of the FD&C Act provided for FDA to issue regulations to require approval of an application for premarket approval for preamendments devices or devices found substantially equivalent to preamendments devices. Section 515(b) of the FD&C Act, as amended by FDASIA, provides for FDA to require approval of an application for premarket approval for such devices by issuing a final order, following the issuance of a proposed order in the **Federal Register**. FDA will continue to codify the requirement for an application for premarket approval, resulting from changes issued in a final order, in the Code of Federal Regulations (CFR). Therefore, under section 515(b)(1)(A) of the FD&C Act, as amended by FDASIA, in the proposed order, we are proposing to require approval of an application for premarket approval for multiple use blood lancets for multiple patient use and, if this proposed order is finalized, we will make the language in 21 CFR 878.4850(d) consistent with the final version of this proposed order.

XII. 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.

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List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878, as proposed to be amended elsewhere in this issue of the **Federal Register**, be further amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add paragraph (d)(3) to § 878.4850, under subpart E, to read as follows:

§ 878.4850 Blood Lancets.

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(d) * * *

(3) *Date PMA or notice of completion of a PDP is required:* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER CALLING FOR PMAs IN THE **FEDERAL REGISTER** OR 30 MONTHS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER RECLASSSIFYING INTO CLASS III, WHICHEVER IS LATER] for any multiple use blood lancet for multiple patient use described in paragraph (d)(1) of this section that was in commercial distribution before May 28, 1976, or that has, on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER CALLING FOR PMAs IN THE **FEDERAL REGISTER** OR 30 MONTHS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER RECLASSSIFYING INTO CLASS III, WHICHEVER IS LATER], been found to be substantially equivalent to a multiple use blood lancet for multiple patient use described in paragraph (d)(1) of this section that was in commercial distribution before May 28, 1976. Any other multiple use blood lancet for multiple patient use shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: February 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–04579 Filed 3–2–16; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–123867–14]

RIN 1545–BM28

Utility Allowances Submetering

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: This document contains proposed regulations that amend the utility allowance regulations concerning the low-income housing credit. The proposed regulations relate to the circumstances in which utility costs paid by a tenant based on actual consumption in a submetered rent-restricted unit are treated as paid by the tenant directly to the utility company. The proposed regulations extend those rules to situations in which a building owner sells to tenants energy that is produced from a renewable source and that is not delivered by a local utility company. The proposed regulations affect owners of low-income housing projects that claim the credit, the tenants in those low-income housing projects, and the State and local housing credit agencies that administer the