

III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other 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 part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. K123250: De Novo Request per section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act From Xlumena, Inc., dated February 15, 2013.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for 21 CFR part 876 continues to read as follows:

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

■ 2. Add § 876.5015 to subpart F to read as follows:

§ 876.5015 Pancreatic drainage stent and delivery system.

(a) *Identification.* A pancreatic drainage stent is a prescription device that consists of a self-expanding, covered, metallic stent, intended for placement to facilitate transmural endoscopic drainage of pancreatic pseudocysts. This stent is intended to be removed upon confirmation of pseudocyst resolution. This device may also include a delivery system.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device and elements of the delivery device that may contact the patient must be demonstrated to be biocompatible.

(2) Performance data must demonstrate the sterility of patient-contacting components of the device.

(3) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the requested shelf life.

(4) Non-clinical testing data must demonstrate that the stent and delivery system perform as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Deployment testing of the stent and delivery system must be conducted under simulated use conditions.

(ii) Removal force testing must be conducted. The removal force testing must demonstrate that the stent can be safely removed, and that the stent will remain in place when subjected to forces encountered during use.

(iii) Expansion force testing must be conducted. The expansion force must demonstrate that the forces exerted by the stent will not damage the tissue surrounding the stent.

(iv) Compression force testing must be conducted. The compression force must demonstrate that the stent will withstand the forces encountered during use.

(v) Dimensional verification testing must be conducted.

(vi) Tensile testing of joints and materials must be conducted. The minimum acceptance criteria must be adequate for its intended use.

(vii) Fatigue testing must be conducted. Material strength must demonstrate that the stent will withstand forces encountered during use.

(viii) Corrosion testing must be conducted. Corrosion resistance must demonstrate that the stent will withstand conditions encountered during use.

(5) Non-clinical testing must evaluate the compatibility of the stent in a magnetic resonance (MR) environment.

(6) Well-documented clinical experience must demonstrate safe and effective use, and capture any adverse events observed during clinical use.

(7) Labeling must include the following:

(i) Appropriate instructions, warnings, cautions, limitations, and information related to the safe use of the device, including deployment of the device, maintenance of the drainage lumen, and removal of the device.

(ii) A warning that the safety and patency of the stent has not been

established beyond the duration of the documented clinical experience.

(iii) Specific instructions and the qualifications and clinical training needed for the safe use of the device, including deployment of the device, maintenance of the drainage lumen, and removal of the device.

(iv) Information on the patient population for which the device has been demonstrated to be effective.

(v) A detailed summary of the clinical experience pertinent to use of the device.

(vi) A detailed summary of the device technical parameters.

(vii) A detailed summary of the device- and procedure-related complications pertinent to use of the device.

(viii) An expiration date/shelf life.

Dated: May 21, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Bureau of Engraving and Printing

31 CFR Part 100

Exchange of Mutilated Paper Currency

AGENCY: Bureau of Engraving and Printing, Treasury.

ACTION: Interim rule.

SUMMARY: The Department of the Treasury, Bureau of Engraving and Printing is amending its regulations on exchange of mutilated paper currency in order to update mutilated currency procedures and eliminate references to obsolete practices and terms. The amendments will serve to deter fraud and abuse in the mutilated currency redemption process.

DATES: Comments must be received no later than July 28, 2014. *Effective date:* May 29, 2014.

ADDRESSES: The Bureau of Engraving and Printing invites comments on all aspects of this interim rule. Comments may be submitted through one of these methods:

Electronic Submission of Comments: Interested persons are encouraged to submit comments electronically through the Federal eRulemaking Portal at <http://www.regulations.gov>. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt, and enables the Department to make them available to the public.

Comments submitted electronically through the <http://www.regulations.gov> Web site can be viewed by other commenters and interested members of the public.

Mail: Comments may be sent to the Office of the Chief Counsel, United States Department of the Treasury, Bureau of Engraving and Printing, 14th and C Streets SW., Washington, DC 20228, Room 419–A, Attention: Amendments to 31 CFR Part 100, Subpart B. Comments will be made available for public inspection upon written request. The Bureau of Engraving and Printing will make such comments available for public inspection and copying at the above listed location, on official business days between the hours of 9 a.m. and 5 p.m. Eastern time. Persons wishing to inspect the comments submitted must request an appointment by telephoning (202) 874–2500. All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Nichole Jenkins Washington, Senior Attorney, Department of the Treasury, Bureau of Engraving and Printing, 14th and C Streets SW., Washington, DC 20228, by phone at (202) 874–2500, or by email at Nichole.Washington@bep.gov.

SUPPLEMENTARY INFORMATION:

Background

The Bureau of Engraving and Printing, a bureau within the Department of the Treasury, last made minor revisions to its regulations pertaining to the redemption of mutilated currency on March 11, 1991. The Bureau of Engraving and Printing is proposing to amend the regulations in order to update mutilated currency procedures and eliminate references to obsolete practices and terms and to provide the public with more specific information on the process for submitting mutilated currency for possible redemption.

This Interim Rule

This rule establishes the process by which members of the public may request redemption of mutilated currency. It also sets forth the steps taken by the Bureau of Engraving and Printing following submission of different categories of mutilated currency.

The first category of amendments relates to general notification to the public concerning redemption of

mutilated paper currency and the characteristics that the mutilated paper currency submissions should possess for possible redemption. (31 CFR 100.5) The revisions also capture formatting changes as the current regulations predate many of the current regulatory format standards.

The second category of amendments serves to notify the public of the present practices in the Bureau of Engraving and Printing's Mutilated Currency Division, and to deter fraud in mutilated currency submissions. (31 CFR 100.7) The Bureau of Engraving and Printing has encountered some schemes where currency is intentionally mutilated in an apparent attempt to defraud the government. The intentionally mutilated currency is often intermingled with other bills in an apparent effort to thwart detection. The interim rule will allow the Mutilated Currency Division examiners to cease processing submissions that appear to be part of an illegal scheme, and instead alert law enforcement officials. The amendments will also inform submitters under what circumstances to provide banking information for purposes of electronic funds transfers.

The third category of amendments would further clarify the requirements for packaging and shipping mutilated currency submissions and update the delivery methods and the appropriate address for shipping purposes. (31 CFR 100.8) Additional amendments were proposed in order to discourage submitters from tampering with or altering their mutilated currency submission in an attempt to preserve it. For example, bills laminated with tape or glued together in previous submissions made it more difficult for mutilated currency examiners to determine if the bills were fraudulent.

The fourth category of amendments serves to put the public on notice that the Director may provide information pertaining to any mutilated currency submission to law enforcement officials or other third parties for purposes of investigation of related criminal activity or for purposes of seeking civil judgment. (31 CFR 100.9) In a further attempt to deter fraud, the amendments also serve to notify potential submitters that they may be held criminally and/or civilly liable, fined, and/or imprisoned for fraudulent submissions.

Procedural Matters

Executive Order 12866

This rule is not a significant regulatory action, as defined in Executive Order 12866.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) generally requires agencies to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute. Because this rule is being issued without prior notice and comment procedures, the provisions of the Regulatory Flexibility Act do not apply.

Inapplicability of Notice and Comment Procedures

This rule is being issued without prior public notice and comment because under 5 U.S.C. 553(b) and (d)(3) good cause exists to determine that prior notice and comment rulemaking is unnecessary and contrary to the public interest. The regulations implemented through this rule update obsolete language and redemption of mutilated currency procedures and provide the public with more specific information on the voluntary process for submitting mutilated currency for possible redemption. The regulations do not adversely affect the rights of the public. Additionally, delay in the effective date of this rule is contrary to the public interest because there are indicators of current fraud schemes aimed at the newly designed next generation \$100 bill which the revisions are specifically designed to deter.

List of Subjects in 31 CFR Part 100

Currency.

For the reasons stated in the preamble, the Bureau of Engraving and Printing amends subpart B of 31 CFR Part 100 as follows:

PART 100—EXCHANGE OF PAPER CURRENCY AND COIN

■ 1. The authority citation for 31 CFR part 100 continues to read as follows:

Authority: 31 U.S.C. 321.

■ 2. Revise subpart B to read as follows:

Subpart B—Request for Examination of Mutilated Currency for Possible Redemption

Sec.
100.5 Mutilated paper currency.
100.6 Destroyed paper currency.
100.7 Treasury's redemption process.
100.8 Packaging and shipping of mutilated currency.
100.9 Notices.

§ 100.5 Mutilated paper currency.

(a) *General.* Lawfully held mutilated paper currency of the United States may be submitted for examination in accord

with the provisions in this subpart. Such currency may be redeemed at face amount if sufficient remnants of any relevant security feature and clearly more than one-half of the original note remains. Fragments of such mutilated currency which are not clearly more than one-half of the original whole note or are lacking sufficient remnants of any relevant security feature will be redeemed at face value only if the Director, Bureau of Engraving and Printing, Department of the Treasury, is satisfied that the missing portions have been totally destroyed. The Director's judgment shall be based on such evidence of total destruction as is necessary and shall be final. Any submission under this subpart shall be deemed an acceptance of all provisions contained herein.

(b) *Definitions.* The following definitions are used in this subpart:

Mutilated currency is currency which has been damaged to the extent that: (i) One-half or less of the original note remains; or

(ii) Its condition is such that its value is questionable and the currency must be forwarded to the Department of the Treasury for the examination by trained experts before any redemption is made.

Unfit currency is currency which is unfit for further circulation because of its physical condition such as torn, dirty, limp, worn or defaced. Unfit currency should not be forwarded to the Department of the Treasury, but may be exchanged at commercial banks.

§ 100.6 Destroyed paper currency.

No relief will be granted on account of lawfully held paper currency which has been totally destroyed.

§ 100.7 Treasury's redemption process.

(a) Lawful holders of mutilated currency may receive a redemption at full value when:

(1) Clearly more than 50% of a note identifiable as United States currency is present along with sufficient remnants of any relevant security feature; or

(2) Fifty percent or less of a note identifiable as United States currency is present and the method of mutilation and supporting evidence demonstrate to the satisfaction of the Treasury that the missing portions have been totally destroyed.

(b) No redemption will be made when:

(1) A submission, or any portion thereof, demonstrates a pattern of intentional mutilation or an attempt to defraud the United States. In such instances, the entire submission will be destroyed or retained as evidence.

(2) A submission appears to be part of, or intended to further, any criminal

scheme. In such instances, the entire submission will be destroyed or retained as evidence.

(3) A submission contains a material misrepresentation of facts.

(4) Fragments and remnants presented are not identifiable as United States currency; or

(5) Fragments and remnants presented which represent 50% or less of a note are identifiable as United States currency but the method of destruction and supporting evidence do not satisfy the Treasury that the missing portion has been totally destroyed.

(c) Lawfully held mutilated currency in a submission that also contains counterfeit currency may be destroyed or retained as evidence, at the discretion of the Director of the Bureau of Engraving and Printing.

(d) All cases will be handled under proper procedures to safeguard the funds and interests of the submitter of lawfully held mutilated currency. In some cases, the amount redeemed will be less than the amount estimated by the submitter. In other cases, the amount redeemed may be greater. The amount redeemed will be determined by an examination made by trained mutilated currency examiners and governed by the above criteria.

(e) The Director of the Bureau of Engraving and Printing shall have final authority with respect to redemptions of mutilated currency submissions.

(f) All submissions for review shall include an estimate of the value of the currency and an explanation of how it came to be mutilated. The submission should also contain the bank account number and routing number for an account of a United States bank since all redemptions of \$500 or more shall be made through Electronic Funds Transfer (EFT).

§ 100.8 Packaging and shipping of mutilated currency.

Mutilated currency examiners are best able to determine the value of the currency when it has been carefully packed and boxed as described below. As a result, failure to follow the directions in this section may result in a denial of redemption:

(a) Regardless of the condition of the currency, do not disturb the fragments more than is absolutely necessary.

(b) If the currency is brittle or inclined to fall apart, pack it carefully in cotton and box it as found, without disturbing the fragments, if possible.

(c) If the currency was in a purse, box, or other container when mutilated, it should be left therein, if possible, in order to prevent further deterioration of the fragments or from their being lost.

(d) If it is absolutely necessary to remove the fragments from the container, send the container with the currency and any other contents found, except as noted in paragraph (g) of this section.

(e) If the currency was flat when mutilated, do not roll, fold, laminate, tape, glue or in any other way alter the currency in an attempt to preserve it.

(f) If the currency was in a roll when mutilated, do not attempt to unroll or straighten.

(g) If coin or any other metal is mixed with the currency, remove carefully. Do not send coin or other metal in the same package with mutilated paper currency, as the metal will break up the currency. Coin should be exchanged in accordance with subpart C of this part.

(h) Mutilated currency shipments must be addressed as follows:

(1) USPS Delivery—Department of the Treasury, Bureau of Engraving and Printing, MCD/OFM, Room 344A, Post Office Box 37048, Washington, DC 20013.

(2) Non Postal Courier (FEDEX/UPS)—Department of the Treasury, Bureau of Engraving and Printing, MCD/OFM, Room 344-A, 14th & C Streets SW., Washington, DC 20228.

§ 100.9 Notices.

(a) The Director may provide information pertaining to any mutilated currency submission to law enforcement officials or other third parties for purposes of investigation of related criminal activity or for purposes of seeking a civil judgment.

(b) Whoever mutilates currency with the intent to render it unfit to be reissued may be fined and/or imprisoned. 18 U.S.C. 333.

(c) Whoever intentionally files a false claim seeking reimbursement for mutilated currency may be held criminally liable under a number of statutes including 18 U.S.C. 287 and 18 U.S.C. 1341 and may be held civilly liable under 31 U.S.C. 3729, *et seq.*

Dated: May 19, 2014.

Larry R. Felix,

Director.

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