whether FDA should consider alternatives to full IRB review of individual patient expanded access, and what alternative approaches may better facilitate access while providing appropriate ethical oversight.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on expanded access to investigational drugs for treatment use. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations.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 §§ 312.305, 312.310, 312.315, and 312.320 have been approved under OMB control number 0910–0014.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default* or *http://www.regulations.gov.*

Dated: May 3, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–11005 Filed 5–8–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. FDA–2013–D–0447]

Draft Guidance for Industry on Charging for Investigational Drugs Under an Investigational New Drug Application—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Charging for Investigational Drugs Under an IND—Qs & As.'' This guidance is intended to provide information for industry, researchers, and physicians on how FDA is implementing its regulation on charging for an investigational drug under an investigational new drug (IND) application. FDA has received a number of questions about how it is implementing the charging regulation. Therefore, FDA is providing this draft guidance in a question and answer format, addressing the most frequently asked questions and answers, including questions about charging for investigational drugs made available under expanded access programs.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 8, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For the Center for Drug Evaluation and Research:

Colleen L. Locicero, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4200, Silver Spring, MD 20993–0002, 301–796–2270.

For the Center for Biologics Evaluation and Research:

Stephen M. Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Charging for Investigational Drugs Under an IND—Qs & As.'' In 2009, FDA amended its regulation concerning charging for investigational new drugs under an IND (August 13, 2009; 74 FR 40872). The new regulation, which went into effect on October 13, 2009, removed paragraph (d) of § 312.7 (21 CFR 312.7) and replaced it with new § 312.8. The new regulation is intended to clarify the circumstances in which charging for an investigational drug in a clinical trial is appropriate, to set forth criteria for charging for an investigational drug for the three types of expanded access for treatment use described in subpart I of 21 CFR part 312, and to clarify what costs can be recovered for an investigational drug. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the draft guidance entitled ''Expanded Access to Investigational Drugs for Treatment Use—Qs & As,'' which is intended to provide information about FDA's implementation of its expanded access regulations (21 CFR part 312, subpart I).

Since § 312.8 has been in effect, FDA has received numerous questions about how it is implementing the regulation and interpreting various provisions. Consistent with the goal of clarifying the requirements for charging for an investigational drug and the types of costs that can be recovered, FDA is providing a draft guidance in a question and answer format, addressing the most frequently asked questions and answers about charging for investigational drug under an IND.

This draft guidance is being issued consistent with FDA's good guidance

practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on charging for an investigational drug under an IND. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance 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 § 312.8 have been approved under OMB control number 0910–0014.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

IV. Electronic Access

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Dated: May 3, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–11006 Filed 5–8–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2013–N–0461]

General and Plastic Surgery Devices: Reclassification of Ultraviolet Lamps for Tanning, Henceforth To Be Known as Sunlamp Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed Order.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify ultraviolet (UV) lamps intended to tan the skin from class I (general controls) exempt from premarket notification to class II (special controls) and subject to premarket notification, and to rename them sunlamp products. FDA is also designating special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the device. FDA is proposing this reclassification on its own initiative based on new information.

DATES: Submit either electronic or written comments on this proposed order by August 7, 2013. See section XI for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0461, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–0461. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section.

Docket: For access to the docket to read background documents or 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: Neil R.P. Ogden, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, rm. 1438, Silver Spring, MD 20993–0002, 301–796–6397.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) 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). One type of general control provided by the FD&C Act is a restriction on the sale, distribution, or use of a device under section 520(e) of the FD&C Act (21 U.S.C. 360j(e)). A restriction under section 520(e) must be implemented through rulemaking procedures, unlike the administrative order procedures that apply to this proposed reclassification under section 513(e) of the FD&C Act, as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144).

Under section 513 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 has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. Applying these procedures, FDA has classified most preamendments device types (some remain unclassified).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified under section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process.