(OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 310.305, 314.80, 314.98, 600.80, and in 21 U.S.C. 379aa have been approved under OMB Control Numbers 0910–0230, 0910–0291, 0910–0308, and 0910–0636.

IV. Electronic Access

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

Dated: March 6, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–5775 Filed 3–8–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0085]

Draft Guidance on Classifying Significant Postmarket Drug Safety Issues; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Classifying Significant Postmarket Drug Safety Issues.'' This draft guidance describes FDA's current approach to classifying a significant postmarket drug safety issue as a ''priority'' tracked safety issue (TSI) or a ''standard'' TSI, with the capability of elevating some priority TSIs to an ''emergency'' status. The draft guidance was developed in connection with the Center for Drug Evaluation and Research's (CDER's) Safety First Initiative.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 8, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201,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. 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm.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: Michie Hunt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6153, Silver Spring, MD 20993–0002, 301–796–3504.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Classifying Significant Postmarket Drug Safety Issues.'' This draft guidance describes CDER's current approach to determining whether a significant postmarket drug safety issue should be classified as a ''priority,'' as a ''standard,'' or as an ''emergency'' tracked safety issue (TSI).

CDER receives a constant flow of information about potential drug safety issues, and the seriousness of reported problems varies widely. Those that CDER determines to be significant safety issues are tracked in the Center's Document Archiving, Reporting, and Regulatory Tracking System (DARRTS), a centralized data base that enables staff working across the Center to share information. To be considered significant, the safety issue of concern must meet certain criteria. In general, CDER considers postmarket safety issues to be significant if they have the potential to lead to any of the following actions:

- Withdrawal of an approved drug from the market.
- Withdrawal of an approved indication.
- Limitations of a use in a specific population or subpopulation.
- Additions or modifications to the Contraindications or Warnings and Precautions sections of the labeling, to the Medication Guide or other required Patient Package Insert, including safety labeling changes required under the Food and Drug Administration Amendments Act (FDAAA).
- Establishment of or changes to the proprietary name/container label/labeling/packaging to reduce the likelihood of medication errors.
- Establishment or modification of a risk evaluation and mitigation strategy (REMS).
- A requirement that a sponsor conduct a safety-related postmarket clinical trial or observational epidemiological study.
- The conduct of a safety-related observational epidemiological study by FDA.

Since the DARRTS safety tracking function was introduced in 2007, about 1,000 TSIs have been entered into the system. Although all of these issues are considered significant, not all TSIs are equally urgent. Furthermore, CDER does not have adequate resources to manage all TSIs equally rapidly. In the past, prioritization of the TSIs has been handled informally and on a case-by-case basis, without an agreed upon framework for establishing priority.

The Center is now seeking to establish a formal framework for assessing the relative urgency of TSIs, so that CDER can direct resources more effectively toward the issues that pose the greatest potential risk for patients. This framework will classify TSIs as ''priority'' or ''standard'' for CDER review. In addition, the Center will recognize a special ''emergency'' category for certain priority TSIs. The use of a formal framework is intended to ensure that staff working in different offices across CDER reaches similar conclusions about the relative urgency of TSIs, and help them direct attention to those that need to be addressed most expeditiously. It will also inform CDER decisions about public drug safety communications, so that health care practitioners and patients receive timely information about safety risks with the greatest public health significance.

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 this topic. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

III. Electronic Access

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

Dated: March 6, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–5777 Filed 3–8–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0167]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Norovirus Serological Reagents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: Norovirus Serological Reagents.'' This guidance document describes a means by which norovirus serological reagents may comply with the requirement of special controls for class II devices. This guidance document is to be implemented immediately as the special control for norovirus serological reagents.

DATES: Submit either electronic or written comments on this guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Class II Special Controls Guidance Document: Norovirus Serological Reagents'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit electronic comments on the 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: Steven Gitterman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 66, Rm. 5518, Silver Spring, MD 20993–0002, 301–796–6694.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying norovirus serological reagents into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for norovirus serological reagents. Section 513(f)(2) of the FD&C Act provides that any person who submits a premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the FD&C Act (21 U.S.C. 360c(f)(1)), request FDA to classify the device under the criteria set forth in section 513(a)(1) of the FD&C Act (21 U.S.C. 360c(a)(1)). FDA will, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing this classification.

II. Significance of Special Controls Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). Because of the timeframes established by section 513(f)(2) of the FD&C Act, FDA has determined that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is for immediate implementation. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's good guidance practices.

FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of norovirus serological reagents classified under § 866.3395 (21 CFR 866.3395). In order to be classified as a class II device under § 866.3395, a norovirus serological reagents must comply with the requirements of special controls; manufacturers must address the issues requiring special controls as identified in the guidance document, either by following the recommendations in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Class II Special Controls Guidance Document: Norovirus Serological Reagents,'' you may either send an email request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1767 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This 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 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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