

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.

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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

of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 2012.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2002-D-0094; (formerly Docket No. 02D-0049)]

Guidance for the Public, Food and Drug Administration (FDA) Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for the public, FDA advisory committee members, and FDA staff, entitled "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers." We are issuing the guidance to help the public, FDA advisory committee members, and FDA staff to understand the public availability of information regarding certain financial interests and waivers granted by FDA to permit individuals to participate in an advisory committee meeting. The guidance provides additional transparency to FDA's advisory committee process beyond current guidance. This guidance finalizes the draft guidance of the same title dated March 2010 and replaces the guidance of the same title dated August 2008.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to Advisory Committee Oversight and Management Staff, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request. 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 on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Michael Ortwerth, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5104, Silver Spring, MD 20993, email: Michael.Ortwerth@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. The Guidance

FDA is announcing the availability of a guidance entitled, "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers." FDA issues guidance documents for FDA staff, applicants and sponsors, and the public that describe the Agency's current views on a subject.

In January 2002, FDA issued draft guidance on "Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees," and requested comments on the draft guidance (formerly Docket No. 02D-0049, now Docket No. FDA-2002-D-0094, 67 FR 6545, February 12, 2002). The draft guidance was limited in application to special government employees (SGEs) participating in advisory committee meetings at which particular matters relating to particular products were discussed. In October 2007, after an internal assessment of FDA's advisory committee process, FDA published a revised draft guidance for public comment (72 FR 61657, October 31, 2007). The Agency reviewed the submitted comments on the January 2002 draft guidance, the October 2007 draft guidance, and the results of the internal assessment of FDA's advisory committee process and issued guidance that expanded public availability of relevant information to include regular Government employees and SGEs, brought additional transparency to FDA's waiver process, and increased the consistency and clarity of the process (73 FR 45459, August 5, 2008) (www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125647.pdf).

In the **Federal Register** of April 22, 2010 (75 FR 21000), FDA issued for public comment "Draft Guidance for the Public, FDA Advisory Committee Members, and FDA Staff: Public Availability of Advisory Committee

Members' Financial Interest Information and Waivers," dated March 2010. The Agency explained that it tentatively concluded it is appropriate for additional information to be disclosed for individuals receiving a waiver of conflict of interest prior to participating in an FDA advisory committee meeting. Specifically, FDA proposed disclosure of the name of the company or institution associated with the financial interest. The Agency based its draft guidance on the expectation that: (1) This information would help the public understand the nature of the potential conflict and FDA's decision-making and that (2) individuals invited as advisory committee members would agree to the inclusion of this level of detail as a routine part of required disclosures. FDA specifically requested comments on whether disclosing the name of the company or institution associated with the financial interest would: (1) Increase the transparency of FDA's decisions regarding advisory committee member participation and (2) not significantly deter current and potential advisory committee members from service on those committees. The draft guidance also included a template for disclosing to the public the financial interests for which waivers are granted, a template for public disclosure of waivers that FDA grants, and FDA's process for making these documents available on its Web site.

We received several comments on the draft guidance. No commenter indicated that the proposed policies would deter participation and most noted that it would increase transparency.

FDA is issuing the draft guidance with minor revisions to improve clarity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the public availability of financial interest information and waivers relating to the disclosure of conflicts of interest for advisory committee members participating in FDA advisory committee meetings. 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