

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at <http://www.fda.gov/cdrh/fedregin.html>.

### VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 013. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: October 10, 2005.

**Linda S. Kahan,**

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

[FR Doc. 05-22267 Filed 11-7-05; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005D-0344]

#### Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Tinnitus Masker Devices; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Tinnitus Masker Devices." The draft guidance describes a means by which tinnitus masker devices may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend the classification regulations for the tinnitus masker presently classified into class II (special controls: labeling) to designate a special control for these devices. The draft guidance is neither final, nor is it in effect at this time.

**DATES:** Submit written or electronic comments on this draft guidance by February 6, 2006.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Class II Special Controls Guidance Document: Tinnitus Masker Devices" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Teresa Cygnarowicz, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2980.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend the classification regulations for tinnitus masker devices presently classified into class II (special controls: labeling) to designate a special control for the devices. The draft guidance document describes a means by which the device may comply with the requirement of special controls for class II devices. Following the effective date of a final rule based on the proposed rule, any firm submitting a 510(k) premarket notification for the device will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

##### II. Significance of Guidance

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 tinnitus masker devices. 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 an approach satisfies the requirements of the applicable statute and regulations.

##### III. Electronic Access

To receive "Class II Special Controls Guidance Document: Tinnitus Masker Devices" by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1555) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

##### IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E), under OMB control number 0910-0120. The labeling provisions addressed in the draft guidance have been approved by OMB under OMB control number 0910-0485.

##### V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic

comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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: October 7, 2005.

**Linda S. Kahan,**

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

[FR Doc. 05-22268 Filed 11-7-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004D-0146]

#### Guidance for Industry: Validation of Analytical Procedures for Type C Medicated Feeds; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#135) entitled "Validation of Analytical Procedures for Type C Medicated Feeds." This guidance represents the agency's current thinking on the characteristics that should be considered during the validation of non-microbiological analytical procedures for the analysis of drugs in Type C medicated feeds included as part of original and supplemental new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) for Type A medicated articles submitted to FDA. This guidance is the first in a series of three guidances that will discuss assay methods for Type C medicated feeds.

**DATES:** Submit written or electronic comments on agency guidance documents at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

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. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Mary G. Leadbetter, Center for Veterinary Medicine (HFV-141), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6964, e-mail: [mleadbet@cvm.fda.gov](mailto:mleadbet@cvm.fda.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the **Federal Register** of April 28, 2004 (69 FR 23209), FDA published a notice of availability for a draft guidance entitled "Validation of Analytical Procedures for Type C Medicated Feeds" giving interested persons until July 12, 2004, to comment on the draft guidance. FDA received no comments on the draft guidance and no substantive changes were made in finalizing this guidance document.

##### II. Paperwork Reduction Act of 1995

According to the Paperwork Reduction Act of 1995, a collection of information must display a valid OMB control number. The existing valid OMB control numbers for this information collection are 0910-0032 and 0910-0154. This guidance contains no new collections of information.

##### III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on the 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 alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

##### IV. Comments

As with all FDA's guidances, the public is encouraged to submit written or electronic comments with new data or other new information pertinent to this guidance. FDA periodically will review the comments in the docket, and where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments should be

identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### V. Electronic Access

Copies of the guidance document entitled "Validation of Analytical Procedures for Type C Medicated Feeds" may be obtained from the CVM Home Page (<http://www.fda.gov/cvm>) and from the Division of Dockets Management Web site (<http://www.fda.gov/ohrms/dockets/default.htm>).

Dated: October 31, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 05-22222 Filed 11-7-05; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Proposed Collection: Indian Health Service Background Investigations of Individuals in Positions Involving Regular Contact With or Control Over Indian Children OPM—306 Request for Public Comment: 30-Day Notice

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Request for Public Comment: 30-day Proposed Information Collection: Indian Health Service Background Investigations of Individuals in Positions Involving Regular Contact With or Control Over Indian Children OPM-306.

**SUMMARY:** In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed information collection projects, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection project was published in the August 3, 2005, **Federal Register** (70 51826) and allowed 60 days for public comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted to OMB.

**PROPOSED COLLECTION:** *Title:* 0917-0028, "Indian Health Service Background Investigations of Individuals in Positions Involving Regular Contact With or Control Over