drug applications (ANDAs) for sodium tetradecyl sulfate injection.

FOR FURTHER INFORMATION CONTACT: J. Kenneth Borgerding, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness, before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)). FDA may not approve an ANDA that does not refer to a listed drug.

Sodium tetradecyl sulfate injection is the subject of NDA 5–970. On August 13, 1946, Elkins Sinn received approval to market sodium tetradecyl sulfate injection. During 2000, Elkins Sinn discontinued manufacture of this product.

On August 13, 2001, Bennett and Company submitted a citizen petition (Docket No. 01P–0350/CP1) under § 10.30 (21 CFR 10.30) to FDA requesting that the agency determine whether sodium tetradecyl sulfate injection was withdrawn from sale for reasons of safety or effectiveness. In addition, on December 6, 2001, Omega Laboratories, Ltd., submitted a citizen petition (Docket No. 01P–0350/CP2) under § 10.30 to FDA making the same request. FDA has reviewed its records and has found no information to indicate that sodium tetradecyl sulfate injection was withdrawn from the market for safety or efficacy reasons. Therefore, FDA concludes that the decision to not manufacture and market the product was not due to safety or efficacy concerns. Accordingly, the agency will maintain sodium tetradecyl sulfate injection in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to sodium tetradecyl sulfate injection may be approved by the agency.

Dated: October 28, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–28400 Filed 11–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0439]

Medical Devices; Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System; Guidance for Industry and FDA.'' This document describes a means by which transcutaneous air conduction hearing aid systems (TACHAS) may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying TACHAS into class II (special controls).

DATES: Submit written or electronic comments on this guidance by February 5, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System; Guidance for Industry and FDA'' 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 two self-addressed adhesive labels 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 guidance.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Eric M. Mann, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION:

I. Background

The TACHAS is intended to compensate for impaired hearing without occluding the ear canal. It consists of an air conduction hearing aid attached to a surgically fitted tube system, which is placed through the soft tissues between the post auricular region and the outer ear canal. This special control guidance document lists the risks to health identified by FDA and describes measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these devices.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying TACHAS into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for the TACHAS device. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the 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 act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, 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 such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), 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 immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices (GGPs) regulation (§ 10.115). The guidance represents the agency's current thinking on TACHAS. 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 statute and regulations. This guidance document is issued as a level 1 guidance consistent with GGPs.

III. Electronic Access

In order to receive the ''Class II Special Controls Guidance Document: Transcutaneous Air Conduction Hearing Aid System; Guidance for Industry and FDA'' via your fax machine, 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 (1414) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

You may obtain a copy of the guidance from the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer. 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 manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. You may access the CDRH home page at http://www.fda.gov/cdrh. You may search for all CDRH guidance documents at http://www.fda.gov/cdrh/guidance.html. Guidance documents are also available on the Dockets Management Branch Internet site at http://www.fda.gov/ohrms/dockets.

IV. Comments

Interested persons may submit to Dockets Management Branch (see **ADDRESSES**) written comments regarding this immediately in effect guidance by (see **DATES**). Two copies of any comments are to be submitted, except that individuals may submit one copy. Identify comments with the docket number found in brackets in the heading of this document. The guidance document and comments received may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 28, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–28399 Filed 11–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4734–N–66]

Notice of Submission of Proposed Information Collection to OMB: Requirements for Notification of Lead-Based Paint Hazards in Federally-Owned Residential Properties and Housing Receiving Federal Assistance

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* December 9, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2539–0009) and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395–2974; E-mail *Lauren_Wittenberg@omb.cop.gov.*

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail *Wayne_Eddins@HUD.gov*; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice Also Lists the Following Information

Title of Proposal: Requirements for Notification of Lead-Based Paint Hazards in Federally-Owned Residential Properties and Housing Receiving Federal Assistance.

OMB Approval Number: 2539–0009.

Form Numbers: None.

Description of the Need for the Information and its Proposed Use: Requirements to provide a pamphlet on lead poisoning prevention to tenants and purchasers, provision of a notice to occupants on the results of hazard evaluation and hazard reduction actions, and special reporting requirements if there is a child with an environmental intervention blood lead level residing in the unit, and record keeping requirements.