approve abbreviated new drug applications (ANDAs) for chymopapain 10,000 units/vial injection.

FOR FURTHER INFORMATION CONTACT: Brian L. Pendleton, 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 drugs 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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

CHYMODIACTIN (chymopapain 10,000 units/vial injection) is the subject of NDA 18–663. CHYMODIACTIN is indicated for the treatment of patients with documented herniated lumbar intervertebral discs whose symptoms and signs, particularly sciatica, have not responded to an adequate period or periods of conservative therapy. FDA approved the NDA for CHYMODIACTIN on November 10, 1982.

On February 12, 2002, ChymoCorp submitted a citizen petition (Docket No. 02P–0068/CP1) under 21 CFR 10.30 requesting that the agency determine whether chymopapain manufactured by Abbott Laboratories under the brand name CHYMODIACTIN was withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that CHYMODIACTIN (chymopapain 10,000 units/vial injection) was not withdrawn from sale for reasons of safety or effectiveness. Abbott Laboratories informed the agency by telephone that the company no longer markets CHYMODIACTIN. FDA has independently evaluated relevant literature and data for possible postmarketing adverse event reports, but has found no information that would indicate this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for the reasons outlined previously, CHYMODIACTIN (chymopapain 10,000 units/vial injection) was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list chymopapain 10,000 units/vial 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 CHYMODIACTIN (chymopapain 10,000 units/vial injection) may be approved by the agency.

Dated: January 15, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–1742 Filed 1–24–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0525]

Medical Devices; Chemical Indicators Premarket Notification [510(k)] Submissions; Draft 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 draft guidance entitled ''Chemical Indicators Premarket Notification [510(k)] Submissions; Draft Guidance for Industry and FDA.'' The document is intended to provide guidance for industry and other interested parties for the submission of chemical indicators such as process indicators, chemical integrators, and air removal indicators used in test packs such as the Bowie Dick Test. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments on this guidance by April 28, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Chemical Indicators Premarket Notification [510(k)] Submissions; Draft 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 labels to assist that office in processing your request, or fax your request to 301–443–8818.

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. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8913, extension 143.

SUPPLEMENTARY INFORMATION:

I. Background

This document is intended for applicants who plan to market chemical indicators for health care facilities. It includes guidance on the submission of premarket notification [510(k)] submissions for process indicators, chemical integrators, and air removal indicators used in test packs such as the Bowie Dick Test. Chemical indicators are an integral part of monitoring sterilization processes in health care facilities because they provide the user with information on the effectiveness of a sterilization process. FDA is issuing this draft guidance because the agency recognizes the importance of providing applicants and other interested parties with specific recommendations for the

submission of premarket notifications for chemical indicators.

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 represents the agency's current thinking on chemical indicators. 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.

III. Electronic Access

In order to receive the document ''Chemical Indicators Premarket Notification [510(k)] Submissions; Draft Guidance for Industry and FDA'' 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 (1420) 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 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 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 or electronic comments regarding this draft guidance. Two copies of any mailed 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 draft guidance document and any comments FDA receives may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 9, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–1684 Filed 1–24–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4818–N–01]

Notice of Proposed Information Collection for Public Comment on the American Housing Survey (AHS)—2003 National Sample

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* March 28, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: the Reports Liaison Officer, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW., Room 8226, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Ronald J. Sepanik at (202)–708–1060, Ext. 5887 (this is not a toll-free number) or Jane Kneessi, Bureau of the Census, HHES Division, Washington, DC 20233, (301)–763–3235 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: 2003 American Housing Survey—National Survey.

OMB Control Number: 2528–0017.

Description of the need for the information and proposed use: The 2003 American Housing Survey-—National Sample (AHS–N) provides a periodic measure of the size and composition of the housing inventory in our country. Title 12, United States Code, Sections 1701Z–1, 1701Z–2(g), and 1701Z–10a mandate the collection of this information.

The 2003 survey is similar to previous AHS–N surveys and collects data on subjects such as the amount and types of housing in the inventory, the physical condition of the inventory, the characteristics of the occupants, the persons eligible for and beneficiaries of assisted housing by race and ethnicity, and the number and characteristics of vacancies.

Policy analysts, program managers, budget analysts, and Congressional staff use AHS data to advise executive and legislative branches about housing conditions and the suitability of policy initiatives. Academic researchers and private organizations also use AHS data in efforts of specific interest and concern to their respective communities.

The Department of Housing and Urban Development (HUD) needs the AHS data for two important uses.

1. With these data, policy analysts can monitor the interaction among housing needs, demand and supply, as well as changes in housing conditions and costs, to aid in the development of housing policies and the design of housing programs appropriate for different target groups, such as first-time home buyers and the elderly.

2. With these data, HUD can evaluate, monitor, and design HUD programs to improve efficiency and effectiveness.

Agency Form Numbers: Computerized Versions of AHS–21, AHS–22 and AHS–23.

Members of affected public: Households.