

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 Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved.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.

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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