have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product PANDEL Cream (hydrocortisone buteprate). PANDEL Cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in patients 18 years of age or older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PANDEL Cream (U.S. Patent No. 4,290,962) from Taisho Pharmaceutical Co. Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 18, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of PANDEL Cream represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PANDEL Cream is 4,165 days. Of this time, 3,078 days occurred during the testing phase of the regulatory review period, 1,087 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: October 6, 1985. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on October 6, 1985.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: March 10, 1994. The applicant claims March 1, 1994, as the date the new drug application (NDA) for PANDEL Cream (NDA 20–453) was initially submitted. However, FDA records indicate that NDA 20–453 was submitted on March 10, 1994.

3. *The date the application was approved*: February 28, 1997. FDA has verified the applicant's claim that NDA 20–453 was approved on February 28, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,096 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before September 14, 1998, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before January 12, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 23, 1998.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 98–18878 Filed 7–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0508]

Medical Devices: Draft Global Harmonization Task Force Study Group 3 Process Validation Guidance; Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Draft Global Harmonization Task Force Study Group 3 Process Validation Guidance.'' The draft guidance document has been created by members of the International Global Harmonization Task Force Study Group 3 (GHTF SG3) to propose harmonized international process validation technical requirements and guidance for the manufacture of medical devices. The agency is requesting public comment regarding the draft guidance document as proposed by the GHTF SG3. Because FDA intends to utilize the GHTF document as guidance for the agency and industry, FDA is also publishing this document for comment under its good guidance practices (GGP's).

DATES: Written comments concerning this draft guidance document must be received by August 14, 1998.

ADDRESSES: Submit written comments concerning the draft guidance document entitled ''Draft Global Harmonization Task Force Study Group 3 Process Validation 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 written requests for single copies on a 3.5'' diskette of the draft guidance document to the Division of Small Manufacturers 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Collin L. Figueroa, Center for Devices and Radiological Health (HFZ–341), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4648.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by governmental regulatory authorities, industry associations, and individual sponsors to promote the international harmonization of regulatory requirements. FDA has participated in numerous efforts to enhance this harmonization and has expressed its commitment to promote the international harmonization of regulatory requirements. As part of this effort, FDA has been actively involved in a Global Harmonization Task Force (GHTF). The GHTF has subsequently formed four study groups, each tasked with aspects designed to facilitate global harmonization.

Study Group 3 of the GHTF drafted the process validation guidance to harmonize quality systems requirements

to ensure manufactured products meet their intended requirements. FDA is committed to publicizing the work product of the GHTF study groups and encourages dissemination of these harmonization documents. Because FDA intends to utilize this GHTF document as guidance for the agency and industry, FDA also is publishing this document for comment under its GGP's. The information and guidance contained in the draft document is intended to help manufacturers understand quality system requirements that involve process validation and how process validation relates to product design and corrective actions.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on global harmonization and process validation. 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 applicable statute, regulations, or both.

The agency has adopted GGP's, which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive the ''Draft Global Harmonization Task Force Study Group 3 Process Validation Guidance'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 2268 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance document may also do so using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. Updated on a regular basis, the CDRH home page includes ''Draft Global Harmonization Task Force Study Group 3 Process Validation Guidance,'' 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. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The ''Draft Global Harmonization Task Force Study Group 3 Process Validation Guidance'' will be available at ''http://www.fda.gov/cdrh/comp/ghtfproc.html'' and ''http://www.fda.gov/cdrh/comp/ghtfproc.pdf''.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select MEDICAL DEVICES AND RADIOLOGICAL HEATLH. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

IV. Comments

Interested persons may, on or before August 14, 1998, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 9, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–19109 Filed 7–14–98; 12:30 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0469]

Draft Guidance for Industry on Labeling of OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis).'' The guidance is intended to provide a general labeling format for all over-the-counter (OTC) drug products for the treatment of vaginal yeast infections. The draft guidance provides recommendations for both the carton and the educational brochure.

DATES: Written comments on the draft guidance may be submitted by October 14, 1998. General comments on the agency guidances are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm.'' Submit written requests for single copies of the draft guidance entitled ''Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Turner, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis).'' Current labeling for such OTC drug products varies widely among manufacturers. However, the content to be communicated in labeling is nearly identical for each product; thus the labeling for these products should convey a clear and consistent message for the consumer. The intent of this document is to provide labeling guidance for all OTC drug products to treat vaginal yeast infections.

Until 1990, topical drug products for the treatment of vulvovaginal candidiasis were available by prescription only. In 1990, FDA convened an advisory committee