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This draft guidance document represents the agency's current thinking on global harmonization and process validation.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Persons interested in obtaining a copy of the draft guidance document may also do so using the World Wide Web (WWW).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

meeting to obtain expert on opinion whether the agency should allow topical therapies to be made available for OTC use. The advisory committee recommended that women whose initial episode of vulvovaginal candidiasis was diagnosed and treated by a physician could adequately self-treat their condition without the supervision of a health care provider. The first 7-day intravaginal drug product for the treatment of vulvovaginal candidiasis was approved for OTC use in 1990; the first 3-day product in 1995; and the first single-dose product in 1997.

In the **Federal Register** of February 27, 1997 (62 FR 9024), the agency published a notice entitled ''Over-the-Counter Human Drugs; Proposed Labeling Requirements,'' proposing a standardized format for the labeling of OTC drug products. This proposed standardized format is frequently referred to as the ''Drug Facts Format.'' The agency is developing this guidance document on labeling for OTC drug products for the treatment of vaginal yeast infections in accordance with the ''Drug Facts Format.''

Labeling for OTC drug products for the treatment of vaginal yeast infections consists of three components: (1) The carton, (2) the educational brochure, and (3) the overwrap. With OTC drug products, the agency believes that labeling takes on the critical role of providing information to the consumer. Therefore, consumers must have information that is easily understood to allow for appropriate self-selection and appropriate use of the product. Since there are a variety of OTC products currently available for the treatment of vaginal yeast infections, and since in most cases, the content to be communicated in labeling is nearly identical for each product, the labeling for these products should convey a clear and consistent message to the consumer. The intent of the draft guidance is to provide labeling guidance for all OTC drug products for the treatment of vaginal yeast infections.

The draft guidance represents the agency's current thinking on the labeling of OTC topical drug products for the treatment of vaginal yeast infections. 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, regulations, or both.

Interested persons may, on or before October 14, 1998, submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. The draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18879 Filed 7–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–116, HCFA–416, HCFA–R–148, and HCFA–R–231]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations in 42 CFR 493.1—.2001; Form No.: HCFA–116 (OMB# 0938–0581); *Use:* These certification requirements have been established for any entity that performs testing on human beings for diagnostic or treatment purposes. If a laboratory conducts relatively simple tests that are categorized as waived or provider performed microscopy test procedures (PPMP), it must obtain a certificate of waiver or certificate of PPMP. If the laboratory conducts any tests outside of these two categories, it must apply for a certificate of compliance or certificate of accreditation and initially obtain a registration certificate. These certificates ensure that laboratories are in compliance with CLIA.; *Frequency:* Biennially; *Affected Public:* Business or other for profit, Not for profit institutions, Federal Government, and State, local or tribal government; *Number of Respondents:* 16,000; *Total Annual Responses:* 16,000; *Total Annual Hours:* 20,000.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic, and Treatment Services (EPSDT) Participation Report and Supporting Regulations in 42 CFR 441.60; *Form No.:* HCFA–416 (OMB# 0938–0354); *Use:* States are required to submit an annual report on the provision of EPSDT services to HCFA pursuant to section 1902(a)(43) of the Social Security Act. These reports provide HCFA with data necessary to assess the effectiveness of State EPSDT programs. It is also helpful in developing trend patterns, national projections, responding to inquiries, and determining a State's results in achieving its participation goal.; *Frequency:* Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,568.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Limitation on Provider-Related Donations and Health Care-Related Taxes; Limitations on Payments to Disproportionate Share Hospitals; Medicaid and Supporting Regulations in 42 CFR 433.68, 433.74, 447.74 and 447.272; *Form No.:* HCFA–R–148 (OMB# 0938–0618); *Use:* These information collection requirements specify limitations on the amount of Federal financial participation available for medical assistance expenditures in a fiscal year. States receive donated funds from providers and revenues are generated by health care related taxes. These donations and revenues are used to fund medical assistance programs.; *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* #3,892.

4. *Type of Information Request:* Revision of a currently approved collection; *Title of Information*