Dated: July 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–18126 Filed 8–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–M–0208]

Medical Devices Regulated by the Center for Biologics Evaluation and Research; Availability of Summaries of Safety and Effectiveness Data for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved by the Center for Biologics Evaluation and Research (CBER). This list is intended to inform the public of the availability through the Internet and FDA's Division of Dockets Management of summaries of safety and effectiveness data of approved PMAs.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please include the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness data.

FOR FURTHER INFORMATION CONTACT: Tiffany Brown, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information on the Internet at *http://www.fda.gov*. In addition, the regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during the quarter. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting administrative reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of PMAs approved by CBER for which summaries of safety and effectiveness data were placed on the Internet from April 1, 2008, through June 30, 2008. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1. LIST OF SUMMARIES OF SAFETY AND EFFECTIVENESS DATA FOR APPROVED PMAS MADE AVAILABLE APRIL 1, 2008, THROUGH JUNE 30, 2008

PMA No./Docket No.	Applicant	Trade Name	Approval Date
BP050051/0/FDA–2008–M–0208	Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostics Products Anti-HIV 1+2 Calibrator, and VITROS Immunodiagnostics Products Anti-HIV 1+2 Reagent Pack	March 27, 2008

II.Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cber/products.htm*.

Dated: July 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–18125 Filed 8–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0413]

Draft Guidance for Industry on Residual Solvents in Drug Products Marketed in the United States; 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 ''Control of Residual Solvents in Drug Products Marketed in the United States.'' On July 1, 2008, the United States Pharmacopeia (USP) published a new test requirement for the control of residual solvents, General Chapter <467> ''Residual Solvents,'' which replaced USP General Chapter <467> ''Organic Volatile Impurities.'' The change affects all compendial drug products marketed in the United States. This draft guidance reflects FDA's recommendations on how to comply with those USP changes.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit

written or electronic comments on the draft guidance by October 6, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Larry Ouderkirk, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4125, Silver Spring, MD 20993, 301–796–1585.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Residual Solvents in Drug Products Marketed in the United States.'' Beginning July 1, 2008, FDA will require that drug products marketed in the United States with an official USP monograph meet the residual solvents requirements in the revised General Chapter <467> ''Residual Solvents.''

For compendial drug products approved under a new drug application (NDA) or abbreviated new drug application (ANDA), changes made to the specifications in the approved application regarding the revised General Chapter <467> should be in accordance with applicable regulations described in 21 CFR 314.70 and the recommendations in the guidance for industry on ''Changes to an Approved NDA or ANDA, April 2004.'' FDA expects that in most cases, an annual report can be used to report changes.

FDA recommends that applicants who have submitted NDAs or ANDAs to the agency for drug products that are not the subject of an official USP monograph control and limit the presence of residual solvents in the subject drug product as described in the guidance on ''Q3C Impurities: Residual Solvents.''

Marketed compendial drug products that are not approved under an NDA or ANDA (for example, over-the-counter (OTC) drug products that are marketed under an FDA OTC monograph) are also subject to the provisions of the Federal Food, Drug, and Cosmetic Act, the revised General Chapter <467>, and current good manufacturing practice requirements in 21 CFR 211.165(e) and 211.194(a)(2).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on control of residual solvents in drug products marketed in the United States. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: July 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–18127 Filed 8–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Advisory Committee for Reproductive Health Drugs; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Advisory Committee for Reproductive Health Drugs.

General Function of the Committee: To provide advice and recommendations to theagency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 8, 2008, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Rockville, Plaza Ballrooms I and II, 1750 Rockville Pike, Rockville, MD. The hotel phone number is 301–468–1100.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: kalyani.bhatt@fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 301–451–2537. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 22–242, proposed trade name FABLYN (lasofoxifene tartrate) Tablets, 0.5 milligrams (mg), Pfizer Inc., for the proposed indication of the treatment of osteoporosis in postmenopausal women at increased risk of fracture.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the