SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' This draft guidance is one of a series of guidance documents intended to assist applicants in drafting prescription drug labeling in which prescribing information is clear and accessible and complying with the new requirements in the final rule on the content and format of labeling for prescription drug and biological products (71 FR 3922, January 24, 2006). This draft guidance is intended to help applicants select information for inclusion in the ''Dosage and Administration'' section of labeling and to help them organize that information.

DATES: Submit written or electronic comments on the draft guidance by July 9, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the 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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Joseph P. Griffin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4204, Silver Spring, MD 20993–0002, 301–796–1077; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products—Content and Format.'' The draft guidance provides recommendations on how to select information for inclusion in the ''Dosage and Administration'' section of labeling and how to organize information within the section. This draft guidance is one of a series guidances FDA is developing, or has developed, to assist applicants and reviewers with the format and content of certain sections of the labeling for prescription drugs. In the **Federal Register** of January 24, 2006 (71 FR 3998 and 3999), FDA issued final guidances on the format and content of the ''Adverse Reactions'' and ''Clinical Studies'' sections of labeling and draft guidances on implementing the new labeling requirements for prescription drugs and the format and content of the ''Warnings and Precautions,'' ''Contraindications,'' and ''Boxed Warning'' sections of labeling. The new labeling requirements (71 FR 3922) and these guidances are intended to make information in prescription drug labeling easier for health care practitioners to access, read, and use.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement 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 the draft guidance. 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.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 201.57 have been approved under OMB control number 0910–0572.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/ohrms/dockets/default.htm*, *http://www.fda.gov/cder/guidance/index.htm,* or *http://www.fda.gov/cber/guidelines.htm*.

Dated: March 30, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6508 Filed 4–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0106]

Draft Guidance for Clinical Investigators, Sponsors, and Investigational Review Boards on Adverse Event Reporting—Improving Human Subject Protection; 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 ''Guidance for Clinical Investigators, Sponsors, and IRBs; Adverse Event Reporting—Improving Human Subject Protection.'' This guidance is intended to assist the research community in interpreting requirements for submitting reports of unanticipated problems, including certain adverse events reports, to the Institutional Review Board (IRB). FDA developed this draft guidance in response to concerns raised by the IRB community that increasingly large volumes of individual adverse event reports are inhibiting rather than enhancing IRBs' ability to adequately protect human subjects. The guidance provides recommendations to IRBs, sponsors, and investigators on improving the usefulness of the adverse event information submitted to IRBs.

DATES: Submit written or electronic comments on the draft guidance by June 8, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Critical Path Programs (HF–18), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800–835–4709 or 301–827–1800. 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Terrie L. Crescenzi, Office of Critical Path Programs (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7864.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for clinical investigators, sponsors, and IRBs entitled ''Guidance for Clinical Investigators, Sponsors, and IRBs; Adverse Event Reporting—Improving Human Subject Protection.'' Under the regulations in 21 CFR part 50 (Protection of Human Subjects), part 56 (21 CFR part 56) (Institutional Review Boards), part 312 (21 CFR part 312) (Investigational New Drug Application), and part 812 (21 CFR part 812) (Investigational Device Exemptions), an IRB must review and approve a clinical study before the study is initiated. Additionally, after an IRB's initial review and approval, an IRB must conduct continuing review of the study at intervals appropriate to the degree of risk presented by the study, at least annually. The primary purpose of both the initial review of a study and the periodic review of the conduct of the study is to assure the protection of the rights and welfare of human subjects. To assure the protection of the rights and welfare of human subjects during the conduct of a clinical study, an IRB must have information concerning unanticipated problems in the study and changes in the research activity. Such information may be important to the IRB's review. This draft guidance discusses adverse event reporting to IRBs by sponsors, and investigators, and emphasizes the greater value of well-analyzed adverse event data to an IRBs review. 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 adverse event reporting for the purpose of improving human subject protection. 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. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 56 have been approved under OMB Control No. 0910–0130; the collections of information in part 312 have been approved under OMB Control No. 0910–0014; and the collections of information in part 812 have been approved under OMB Control No. 0910–0078.

III. 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.

IV. 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.fda.gov/ohrms/dockets/default.htm*.

Dated: April 2, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–6595 Filed 4–6–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0117]

Draft Guidance for Industry on Orally Disintegrating Tablets; 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 ''Orally Disintegrating Tablets.'' The draft guidance provides pharmaceutical manufacturers of new and generic drug products with an agency perspective on the definition of an orally disintegrating tablet (ODT) and also provides recommendations to applicants who would like to designate a proposed product as an ODT.

DATES: Submit written or electronic comments on the draft guidance by June 8, 2007. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), 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 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Frank O. Holcombe, Jr., Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–9310.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Orally Disintegrating Tablets.'' The draft guidance provides pharmaceutical manufacturers of new and generic drug products with an agency perspective on the definition of an ODT and also provides recommendations to applicants who would like to designate proposed products as ODTs.