Dated: May 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12897 Filed 5–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0456]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Conditions for the Use of Narcotic Drugs for Treatment of Narcotic Addiction, Reporting and Recordkeeping Requirements,'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 25, 1997 (62 FR 62773), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0140. The approval expires on April 30, 2001.

Dated: May 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12902 Filed 5–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0287]

Guidance for Industry on Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing.'' This is revision 1 of the guidance. The guidance has been revised to reflect the recent availability of buspirone hydrochloride tablets in 15-milligram dosage forms. Bioequivalence is tested using the highest available dosage of the reference listed drug. The revised guidance also notes the nonlinearity of buspirone at multiple-dosing.

DATES: Written comments on agency guidance documents may be submitted at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of ''Buspirone Hydrochloride Tablets In Vivo Bioequivalence and In Vitro Dissolution Testing'' 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 requests. Submit written comments on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sikta Pradhan, Center for Drug Evaluation and Research (HFD–652), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5847.

SUPPLEMENTARY INFORMATION: This guidance document is a level 2 guidance document consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on buspirone hydrochloride tablets in vivo bioequivalence and in vitro dissolution testing. 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 statute, regulations, or both.

Interested persons may submit written comments on the guidance at any time to the Dockets Management Branch (address above). 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 guidance 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: May 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12903 Filed 5–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0276]

Guidance for Industry on Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Standards for the Prompt Review of Efficacy Supplements, Including Priority Efficacy Supplements.'' As required by the Food and Drug Administration Modernization Act of 1997 (Modernization Act), this guidance for industry describes the standards for the prompt review of efficacy supplements. It also is intended to define those efficacy supplements that are eligible for priority review.

DATES: Written comments may be submitted on the guidance document by August 13, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm, or http://www.fda.gov/cber/guidelines.htm. Submit written comments on this guidance to the Dockets Management Branch (HFD–305), Food and Drug Administration,

12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments are to be identified with the docket number found in brackets in the heading of this document. After the comment period, comments may be submitted to one of the centers at the addresses below.

FOR FURTHER INFORMATION CONTACT:

Joseph P. Griffin, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION: Section 403(a) of the Modernization Act requires that FDA publish in the **Federal Register** standards for the ''prompt review of supplemental applications submitted for approved articles * * *.'' The legislative history indicates that this provision was directed at certain types of efficacy supplements, i.e., supplemental applications proposing to add a new use of an approved drug to the product labeling.[1] Section 403(b)(3) of the Modernization Act requires that FDA provide guidance to define supplemental applications that are eligible for priority review. This guidance document fulfills both Modernization Act requirements.

Section 101 of the Modernization Act reauthorized for an additional 5 years, with certain technical changes, the user fee program described in the Prescription Drug User Fee Act of 1992. Section 101 of the Modernization Act directed that the user fees authorized by the amendments in that subtitle be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the performance goals identified in letters from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate, as set forth in the Congressional Record. The referenced performance goals include standards for the review of efficacy supplements and distinguish between priority and standard supplements. The guidance also defines ''priority'' for purposes of applying the performance goals.

The guidance document is being issued as a Level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It is being implemented without prior public comment because the guidance is needed to implement the Modernization Act. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance document represents the agency's current thinking on the standards for the prompt review of efficacy supplements. 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, at any time, submit written comments on the guidance document to the Dockets Management Branch (address above). 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 guidance document and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 8, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–12900 Filed 5–14–98; 8:45 am]

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[1] See U.S. Congress, Senate Committee on Labor and Human Resources, ''Food and Drug Administration Modernization Act of 1997,'' S. Rept. 105–43 on S. 830, pp. 41–42, 105th Cong., 1st sess., 1 July 1997; and House Committee on Commerce, ''Prescription Drug User Fee Authorization and Drug Regulation Act of 1997,'' H. Rept. 105–310 on H.R. 1411, pp. 63–64, 105th Cong., 1st sess., 7 October 1997.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0100]

Guidance for Industry on Providing Clinical Evidence of Effectiveness for Human Drugs and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products.'' The purpose of this guidance is to clarify what clinical evidence of effectiveness should be provided in new drug applications, biological product license applications, and supplemental applications for new uses of drugs and biologics. The guidance is also intended to fulfill the requirements of certain provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act).

DATES: General comments on agency guidance documents are welcome at any time.

ADDRESSES: An electronic version of this guidance is available via the Internet at http://www.fda.gov/cder/guidance/index.htm and at http://www.fda.gov/cber/guidelines.htm. Submit written comments on this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Joseph P. Griffin, Center for Drug Evaluation and Research (HFD–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400.

SUPPLEMENTARY INFORMATION: The draft guidance for industry entitled ''Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products'' (the draft guidance) was initially developed as part of an effort to get more information about valid uses of marketed drugs into the labeling of these drugs. Uncertainty on the part of the industry about the evidentiary requirements for demonstrating effectiveness for a supplemental indication was believed to be an obstacle to sponsors submitting applications for supplemental indications. The draft guidance was intended to clarify the amount and types of evidence that could be used to demonstrate effectiveness and thereby facilitate submission of additional supplemental applications. In the **Federal Register** of March 21, 1997 (62 FR 13650), FDA announced the availability of the draft guidance. The notice gave interested persons an opportunity to submit comments by May 20, 1997.

On November 21, 1997, the President signed the Modernization Act (Pub. L. 105–115), which addressed both the standards for providing clinical evidence of effectiveness and the evidentiary requirements for supplemental applications. Section 115 of the Modernization Act amended the definition of substantial evidence in section 505(d) of the Federal Food,