PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application which have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: June 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–17799 Filed 7–8–97; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0267]

Guidance for Industry on Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron.'' The guidance document provides information to manufacturers of iron-containing drug products who are affected by a final rule that requires label warning statements and unit-dose packaging for solid oral drug products that contain 30 milligrams (mg) or more of iron per dosage unit. The guidance document describes the circumstances under which the agency does not intend to object, for a limited period of time, to modified expiration dating by drug manufacturers and packagers who are required to package their products into unit-dose containers under the final rule.

DATES: Written comments may be submitted at any time. The agency does not expect to be guided by the recommendations in this guidance document after July 15, 1999.

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron'' 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.

FOR FURTHER INFORMATION CONTACT: Barry Rothman, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0098.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron.'' The purpose of this guidance document is to describe an approach to stability testing and expiration dating for a limited class of iron-containing products for certain manufacturers and packagers of drug products containing iron. In the **Federal Register** of January 15, 1997 (62 FR 2218), FDA issued a final rule entitled ''Iron-Containing Supplements and Drugs: Label Warning Statements and Unit-Dose Packaging Requirements'' (hereinafter called the iron regulations). The iron regulations, effective July 15, 1997, require label warning statements and unit-dose packaging for solid oral drug products that contain 30 mg or more of iron per dosage unit.

FDA requires that drug products bear an expiration date determined by appropriate stability testing §§ 211.137 and 211.166 (21 CFR 211.137 and 211.166). Drug product stability needs to be evaluated over time in the same container-closure system that will be used in the marketing of the product, and accelerated stability studies can be used to support tentative expiration dates in the event that full shelf life studies are not available. When a firm changes the packaging of a drug product, stability testing must be performed on the product in its new packaging, and expiration dating must reflect the results of the new stability testing.

To meet the requirements of the iron regulations, all manufacturers of solid oral drug products that contain 30 mg or more of iron per dosage unit must package their products in unit-dose packaging. As a result, these manufacturers must determine an appropriate expiration date for that packaging. Because the final iron regulations were published only 6 months before they were to take effect, accelerated stability testing may be necessary to justify an expiration date of more than 6 months. However, accelerated stability studies are impractical for some drug products containing iron, especially multivitamin products, because such products often do not perform well under the artificially stressful conditions of accelerated studies. For these drug products, real-time stability testing may be the only method to determine an appropriate expiration date. To minimize the burden faced by those manufacturers and packagers who have made good faith efforts to comply with the stability testing requirements but were unable to do so, FDA advises that, for a limited period of time, it does not intend to object if such a firm fails to comply with §§ 211.137 and 211.166, so long as it establishes expiration dates and stability testing protocols under the specific approach described in the guidance document. FDA expects that sufficient stability testing will be performed in a timely fashion; therefore, the agency does not expect to be guided by the recommendations in this guidance document after July 15, 1999.

This guidance document represents the agency's current thinking on expiration dating for solid oral drug products containing 30 mg or more of iron. 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, at any time, submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one copy. Requests and comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

An electronic version of this guidance is also available on the Internet using the World Wide Web at http://www.fda.gov/cder/guidance.htm.

Dated: June 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–17796 Filed 7–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Folate Intake; Dissemination of Public Health Message; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a meeting to be held in collaboration with the Centers for Disease Control and Prevention and the March of Dimes Birth Defects Foundation. The topic of this meeting concerns the importance of adequate folate intake among women of child-bearing age in reducing the risk of certain birth defects. The agencies involved in the meeting will present relevant background information and information about possible approaches to disseminating information on adequate folate intake.

DATES: The meeting will be held on Wednesday, August 6, 1997, from 10 a.m. to 12 p.m. Registration for this meeting must be received by July 30, 1997.

ADDRESSES: The meeting will be held at the Hubert H. Humphrey Bldg., 1st Floor Auditorium, 200 Independence Ave. SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Jeanne E. Latham, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, Federal Bldg. 8, 200 C St. SW., rm. 4129 B, Washington, DC 20204, 202–205–4697, FAX 202–260–8957.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage and to provide guidance to attendees, including manufacturers and marketers of women's products and others, who may wish to assist in the dissemination of a public health message about adequate folate intake. To register for the meeting, please call or fax the contact person (address above). Include the name, title, telephone, and fax number of the person attending and the name of the organization being represented.

If special accommodations are required due to a disability, please contact Jeanne Latham at least 7 days before the meeting.

Dated: June 30, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–17798 Filed 7–8–97; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Funds for the Nursing Education Loan Repayment Program for Service in Certain Health Facilities

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of available funds.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year (FY) 1997 for awards under section 846 of the Public Health Service (PHS) Act to repay up to 85 percent of the nursing education loans of registered nurses who agree to serve for not less than 2 years as nurse employees in certain health facilities.

The HRSA, through this notice, invites applications for participation in this loan repayment program. Approximately $2,197,000 will be available, and with these funds, the HRSA estimates that approximately 195 loan repayment awards may be made.

The PHS is committed to achieving the health promotion and disease prevention objectives of *Healthy People 2000*, a PHS-led national activity for setting health priorities. These programs will contribute to the *Healthy People 2000* objectives by improving access to primary health care services through coordinated systems of care for medically underserved populations in both rural and urban areas. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report, Stock No. 017–001–00474–01) or *Healthy People 2000* (Summary Report, Stock No. 017–001–00473–01) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402–9325 (telephone number: 202–783–3238).

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

DATES: To receive consideration for funding, individuals must submit their applications by August 31, 1997. Applications shall be considered as meeting the deadline if they are either:

(1) received on or before the deadline date; or

(2) sent on or before the deadline and received in time for submission to the reviewing program official.

(Applicants should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late applications will not be considered for funding in FY 1997, but may be kept on file for consideration in FY 1998.

ADDRESSES: Application materials with a list of counties (parishes) with the greatest shortage of nurses may be obtained by calling or writing to: Sharley Chen, Chief, Loan Repayment Programs Branch, Division of Scholarships and Loan Repayments, Bureau of Primary Health Care, HRSA, 4350 East-West Highway, 10th Floor, Bethesda, MD 20814, (301–594–4400). The 24-hour toll-free phone number is 1–800–435–6464 and the FAX number is (301) 594–4981. Completed applications should be mailed to the same address. The application form has been approved under Office of Management and Budget (OMB) Number 0915–0140.

FOR FURTHER INFORMATION CONTACT: For further program information and technical assistance, please contact the Branch Chief at the above address, phone or FAX number.

SUPPLEMENTARY INFORMATION: Section 846 of the PHS Act provides that the Secretary will repay a portion of an individual's educational loans incurred for nursing education costs if that individual enters into a contract with the Secretary to serve as a registered nurse for not less than 2 years in a variety of eligible health facilities or in a health facility determined by the Secretary to have a critical shortage of nurses. Due to funding limitations, the total outstanding educational loan balances eligible for loan repayment assistance will not exceed $30,000.00. For an individual who is selected to participate in this program, repayment shall be on the following basis:

(1) By the completion of the first year of agreed service, the Secretary will