DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1195]

Draft Guidance for Industry on Bioanalytical Methods Validation for Human Studies; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bioanalytical Methods Validation for Human Studies.'' This draft guidance provides assistance to sponsors and applicants of investigational new drug applications (IND's), new drug applications (NDA's), abbreviated new drug applications (ANDA's), and supplements, in developing validation information for bioanalytical methods used in human clinical pharmacology, bioavailability, and bioequivalence studies. This draft guidance does not cover analytical methods used for nonhuman pharmacology/toxicology studies, chemistry, manufacturing, and controls information, or in vitro dissolution studies.

DATES: Written comments may be submitted on the draft guidance document by March 8, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of ''Bioanalytical Methods Validation for Human Studies'' 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 Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vinod P. Shah, Center for Drug Evaluation and Research (HFD–350), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5635.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Bioanalytical Methods Validation in Human Studies.'' This draft guidance is based primarily on the report of a conference on Analytical Methods Validation: Bioavailability, Bioequivalence and Pharmacokinetic Studies, held on December 3 to 5, 1990, sponsored by FDA, the American Association of Pharmaceutical Scientists, Federation Internationale Pharmaceutique, the Canadian Health Protection Branch, and Association of Official Analytical Chemists.

This draft level 1 guidance document is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on bioanalytical methods validation in human studies. 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 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. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft 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: December 24, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–69 Filed 1–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1164]

Food Additive Petition Expedited Review—Guidance for Industry and Center for Food Safety and Applied Nutrition Staff; 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 ''Food Additive Petition Expedited Review—Guidance for Industry and Center for Food Safety and Applied Nutrition Staff.'' FDA believes it is in the interest of enhanced food safety to review petitions for certain food additives in an expedited manner. Expedited review will be considered when an additive is intended to decrease incidences of foodborne illnesses through its antimicrobial actions against human pathogens that might be present in food.

DATES: Written comments concerning this guidance may be submitted at any time.

ADDRESSES: Written comments concerning this guidance may be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of the guidance to the Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St. SW., Washington DC 20204, or by telephone to the Office of Premarket Approval at 202–418–3100 (voice), or FAX 202–418–3131. All requests should identify the guidance by its title of ''Food Additive Petition Expedited Review—Guidance for Industry and Center for Food Safety and Applied Nutrition Staff.'' See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 200 C St. SW., Washington DC 20204–0001, 202–418–3074.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) provides for the approval of the use of food additives that are shown to be safe for their intended use. Section 409 of the act (21 U.S.C. 348) provides for the filing of petitions to request such approval, and also authorizes FDA (by delegation) to initiate the approval process. The agency receives food additive petitions for a broad range of proposed uses, including petitions proposing the approval of a substance for use in reducing the number of pathogens in or on food.

FDA believes it is in the interest of enhanced food safety to review petitions for certain food additives in an expedited manner. Expedited review will generally be considered when an additive is intended to decrease the incidence of foodborne illness through its antimicrobial action against human pathogens that might be present in food.

Designating a food additive petition for expedited review means that the food additive petition would be reviewed ahead of other pending food additive petitions, i.e., the petition will be placed at the beginning of the appropriate review queues. All other aspects of the review process (e.g., data requirements for the petition, procedures for evaluating petitions and communicating with petitioners) will be the same for an expedited review petition as for all other food additive petitions.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the procedures to be followed for expedited review of food additive petitions. 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.

The guidance document entitled ''Food Additive Petition Expedited Review—Guidance for Industry and Center for Food Safety and Applied Nutrition Staff'' is a Level 1 guidance under the agency's Good Guidance Practices (62 FR 8961, February 27, 1997). Level 1 guidance documents are generally subject to public comment prior to implementation. However, public comment prior to implementation of this guidance document is not required because there is a public health justification for immediate implementation.

III. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding the 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 guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Such comments will be considered when determining whether to amend the guidance.

IV. Electronic Access

The guidance may also be accessed at the Center for Food Safety and Applied Nutrition home page on the World Wide Web at ''http://www.fda.gov/cfsan''.

Dated: December 15, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–70 Filed 1–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95D–0349]

Draft Guidance for Industry on SUPAC–SS: Nonsterile Semisolid Dosage Forms, Manufacturing Equipment Addendum; 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 ''SUPAC–SS: Nonsterile Semisolid Dosage Forms, Manufacturing Equipment Addendum.'' This draft guidance is intended to provide recommendations to pharmaceutical manufacturers using the Center for Drug Evaluation and Research's guidance for industry, ''SUPAC–SS Nonsterile Semisolid Dosage Forms, Scale-Up and Post Approval Changes: Chemistry Manufacturing and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation'' (SUPAC–SS).

DATES: Written comments on the draft guidance document may be submitted by March 8, 1999. General comments on agency guidance documents 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.'' Written requests for single copies of the draft guidance for industry should be submitted to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5633.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''SUPAC–SS: Nonsterile Semisolid Dosage Forms, Manufacturing Equipment Addendum.'' This document should be used in conjunction with the guidance for industry, ''SUPAC–SS Nonsterile Semisolid Dosage Forms, Scale-Up and Post Approval Changes: Chemistry Manufacturing and Controls; In Vitro Release Testing and In Vivo Bioequivalence Documentation'' (SUPAC–SS), which published in June 1997 (62 FR 32352, June 13, 1997), in determining what documentation should be submitted to FDA regarding equipment changes made in accordance with the recommendations of the SUPAC–SS guidance document.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). This draft guidance represents the agency's current thinking on equipment changes under SUPAC–SS. 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 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. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 24, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–29 Filed 1–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0401]

''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product;'' Availability

AGENCY: Food and Drug Administration, HHS.