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Draft Guidance for Industry on SUPAC–SS: Nonsterile Semisolid Dosage Forms, Manufacturing Equipment Addendum; Availability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.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product.'' The guidance document provides guidance to applicants on the content and format of the chemistry, manufacturing and controls (CMC) and establishment description sections of the ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use'' (revised Form FDA 356h) for vaccines or related products. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and the FDA Modernization Act of 1997, and is intended to reduce unnecessary burdens for industry without diminishing public health protection.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product.'' This guidance document is intended to provide guidance to applicants in completing the CMC section and the establishment description information of revised Form FDA 356h. The guidance announced in this notice supersedes the draft guidance entitled ''Guidance for Industry: Content and Format of Chemistry, Manufacturing and Controls Information and Establishment Description Information for a Vaccine or Related Product'' announced in the **Federal Register** of June 19, 1998 (63 FR 33686). In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of Form FDA 356h that will be used as a single harmonized application form for all drug and licensed biological products. Manufacturers may voluntarily begin using this form for vaccines or related products. FDA will announce in the future when manufacturers are required to use this form for all products. Use of the new harmonized Form FDA 356h will allow a biologic product manufacturer to submit one biologics license application instead of two separate applications (product license application and establishment license application).

This guidance document represents FDA's current thinking on the content and format of the CMC and establishment description sections of a license application for a vaccine or related product. 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. As with other guidance documents, FDA does not intend this guidance document to be all-inclusive and cautions that not all information may be applicable to all situations. The guidance document is intended to provide information and does not set forth requirements.

II. Comments

Interested persons, may at any time, submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document by using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: December 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–30 Filed 1–4–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; Physician Survey on Cancer Susceptibility Testing

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes of Health (NIH), the National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Physicians Survey on Inherited Cancer Susceptibility Testing. Type of Information Collection Request: New. Need and Use of Information Collection: The Physicians Survey on Inherited Cancer Susceptibility Testing will be used by the National Cancer Institute to establish baseline information on the prevalence of genetic testing for cancer susceptibility among primary care physicians in the United States. The survey will assess whether there are statistically significant differences in (1) self-reported knowledge, current use of, and future intentions to use genetic testing for cancer susceptibility, and (2) perceptions of barriers to testing, among primary care physicians by their type and location of practice, and recency of training. Primary care physicians (internists, pediatricians, family and general practitioners) will also be compared with specialty groups (gastroenterologists, surgeons, urologists and oncologists) with respect to their