

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.*

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#### Draft Guidance for Industry on SUPAC-SS: Nonsterile Semisolid Dosage Forms, Manufacturing Equipment Addendum; Availability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

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## 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.