



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0362]

**Site Specific Stability Data for Drug and Biologic Applications; Public Meeting;
Request for Comment**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on site specific stability data for drug and biologic applications. The agency has scheduled the public meeting to discuss scientific issues related to a section of the draft guidance entitled "Draft Guidance for Industry—Stability Testing of Drug Substances and Drug Products." Specifically, the agency will discuss the section of the draft guidance entitled "Site-Specific Stability Data for Drug and Biologic Applications." The agency invites comments on issues related to the meeting.

DATES: The public meeting will be held on March 31, 1999, from 9 a.m. to 2 p.m. Submit written notices of participation by March 24, 1999. Submit written comments on the specific issues of the meeting by (*insert date 90 days after date of publication in the Federal Register*).

ADDRESSES: The public meeting will be held at the Holiday Inn Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814. Submit written notices of participation to Kimberly L. Topper or Angie Whitacre (addresses below). Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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.

FOR FURTHER INFORMATION CONTACT: Kimberly L. Topper or Angie Whitacre, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or e-mail topperk@cder.fda.gov.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 24, 1999. Oral presentations from the public will be scheduled. Time allotted for each presentation may be limited. Those persons desiring to make formal oral presentations should notify the contact

person before March 24, 1999 (providing name, firm name, address, and telephone number), and submit a brief statement of the general nature of the evidence or arguments they wish to present, and an indication of the approximate time requested to make their presentation.

Dated: March 9, 1999

March 9, 1999



William K. Hubbard
Acting Deputy Commissioner for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

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