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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Training on Electronic Records; Electronic Signatures; Satellite Conference;  
Public Meeting

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of satellite conference and public meeting.

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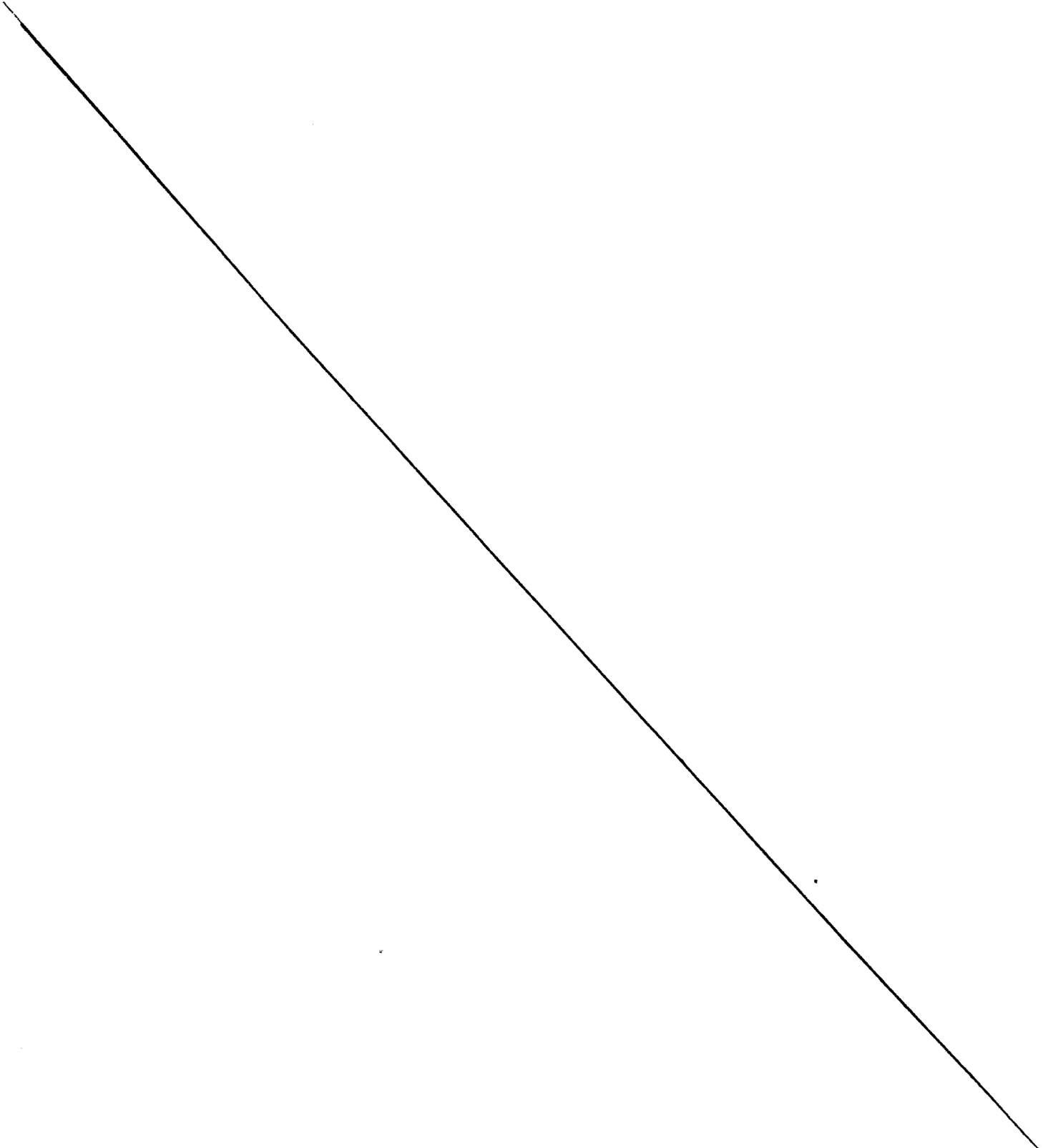
The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Center for Biologics Evaluation and Research, Center for Food Safety and Applied Nutrition, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, and the Center for Veterinary Medicine) is announcing the following satellite conference and public meeting entitled "Industry Training on 21 CFR Part 11." The topics to be discussed are current good manufacturing practices, electronic recordkeeping requirements, validation of electronic recordkeeping systems, and the answers to frequently asked questions.

*Date and Time:* The satellite conference and public meeting will be held on Thursday, October 21, 1999, 1 p.m. to 4 p.m., eastern standard time.

*Contact:* Laura C. Woolf, Center for Biologics Evaluation and Research (HFM-40), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301-827-3840, FAX 301-827-3843, e-mail: woolf@cber.fda.gov.

**SUPPLEMENTARY INFORMATION:** The satellite conference announced in this document is a repeat of the satellite conference at the public meeting announced in the **Federal Register** of December 14, 1998 (63 FR 68778). The satellite conference is intended to inform FDA-regulated industries, and especially, small business about the requirements for electronic recordkeeping according to 21 CFR part 11 and to provide for a dialogue with FDA. The satellite conference addresses the requirements of both the Small Business Regulatory Enforcement Fairness Act (Public Law 104-

121) that mandates outreach activities by Government agencies directed to small businesses and section 406(b) of the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115) that calls for involvement of FDA with its stakeholders in cooperative activities to ensure the quality of marketed products.



There are no meeting sites and registration is not necessary for the satellite conference and public meeting. To view the satellite conference, companies with satellite capability will need to downlink the coordinates. The coordinates are as follows: C Band Galaxy 6 @ 99 west Transponder 20.

Dated: September 30, 1999



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William K. Hubbard  
Senior Associate Commissioner for  
Policy, Planning and Legislation

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

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