helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health by educating regulated industry on FDA requirements to produce safe and effective drug products. FDA has made assurance of safe and effective drug products a high priority.

The workshop helps to implement the objectives of section 406 of the FDA Modernization Act (21 U.S.C. 393) and the FDA Plan for Statutory Compliance, which includes working more closely with stakeholders and ensuring access to needed scientific and technical expertise. The workshop also furthers the goals of the Small Business Regulatory Enforcement Fairness Act (Public Law 104–121) by providing outreach activities by Government agencies directed to small businesses.

Dated: January 28, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2603 Filed 2–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1540]

Withdrawal of Draft Guidance for Industry on Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal of a draft guidance entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records.''

DATES: February 4, 2003.

FOR FURTHER INFORMATION CONTACT: Randall L. Woods, Center for Drug Evaluation and Research (HFD–324), Food and Drug Administration, Metro Park North I, 7520 Standish Pl., rm. 265, Rockville, MD 20855, 301–827–0065.

SUPPLEMENTARY INFORMATION:

I. Background

On August 21, 2002, FDA announced that it was undertaking a new initiative to enhance FDA's current good manufacturing practice program (the CGMP initiative). This new initiative will focus FDA's resources and regulatory attention on those aspects of manufacturing that pose the greatest risk, ensure that FDA's work does not impede innovation, and enhance the consistency of FDA's regulatory approach among the various components. More information on FDA's announcement of this new initiative can be found on FDA's Web site at *www.fda.gov/bbs/topics/NEWS/2002/NEW00829.html*, or a copy of the press release (Ref. 1) may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please reference the docket number found in brackets in the heading of this document.

Under the new initiative, primary responsibility for implementing part 11 (21 CFR Part 11); Electronic Records; Electronic Signatures has shifted to the Center for Drug Evaluation and Research, with continued involvement from other Centers and the Office of Regulatory Affairs.

On November 12, 2002 (67 FR 68674), the agency issued a draft guidance for industry entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records.'' The agency wishes to limit the time spent by industry reviewing and commenting on the guidance, which may no longer represent FDA's approach under the CGMP initiative. The agency may decide to reissue the draft guidance once it has reviewed it under the CGMP initiative.

II. Reference

The following reference is on display at the Dockets Management Branch (see section I of this document) and may be seen by interested parties between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Food and Drug Administration press release, ''FDA Unveils New Initiative To Enhance Pharmaceutical Good Manufacturing Practices,'' August 21, 2002.

Dated: January 28, 2003.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 03–2602 Filed 2–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0023]

Guidance for Industry on Prussian Blue for Treatment of Internal Contamination With Thallium or Radioactive Cesium; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that we have concluded that prussian blue, when produced under conditions specified in approved new drug applications (NDAs), can be found to be safe and effective for the treatment of internal contamination with radioactive thallium, nonradioactive thallium, or radioactive cesium. We encourage the submission of NDAs for prussian blue drug products. We are also announcing the availability of a guidance for industry entitled ''Prussian Blue Drug Products—Submitting a New Drug Application.'' This guidance is intended to assist manufacturers who plan to submit NDAs for prussian blue.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit NDAs to the Food and Drug Administration, Center for Drug Evaluation and Research, Central Document Room, 12229 Wilkins Ave., Rockville, MD 20852. Submit requests for copies of draft labeling to the Division of Medical Imaging and Radiopharmaceutical Drug Products, (HFD–160), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7510. Copies of the reports referred to in this document will be on display at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), 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 guidance to the Dockets Management Branch (address provided in third sentence of this paragraph). Submit electronic comments to http://www.fda.gov/dockets/ecomments. See