H. Independent biological or therapeutic effects on humans

As noted, section 301(ll)(3) provides an exception to the prohibition of adding a drug or biological product to a food if use of the drug or biological product is ''to enhance the safety of the food * * * and not to have independent biological or therapeutic effects on humans.''

1. What factors should FDA consider in determining whether the use of a substance in food is to have a ''biological'' effect on humans?

2. What factors should FDA consider in determining whether the use of a substance in food is to have a biological effect on humans that is ''independent?''

3. What factors should FDA consider in determining whether the use of a substance in food is to have a ''therapeutic'' effect on humans?

4. What factors should FDA consider in determining whether the use of a substance in food is to have a therapeutic impact on humans that is ''independent?''

I. In the Secretary's Discretion

Section 301(ll)(2) permits the addition of a drug or biological product to a food ''if the Secretary, in the Secretary's discretion, has issued a regulation after notice and comment, approving the use * * * in food.'' As noted, the Secretary has delegated his authority under the act to the Commissioner of Food and Drugs.

1. What factors should the Commissioner consider in exercising his discretion under section 301(ll)(2)?

2. What should be the impact, if any, on the exercise of the Commissioner's discretion where use of the drug or biological product in food has been the subject of another statutory or administrative process (e.g., a food contact substance notification that is effective under section 409(h))?

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: July 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17356 Filed 7–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–P–0300] (formerly 2007P–0326)

Determination That SANOREX (Mazindol) Tablets 1 and 2 Milligrams Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness; Correction

AGENCY: Food and Drug Administration. HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that appeared in the **Federal Register** of July 15, 2008 (73 FR 40582). The document announced the determination that SANOREX (mazindol) Tablets, 1 and 2 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy and Planning (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. E8–15998, appearing on page 40582 in the **Federal Register** of Tuesday, July 15, 2008, the following correction is made:

1. On page 40582, in the third column, in the headings section of the document, ''[Docket No. FDA–2007–P–0326]'' is corrected to read ''[Docket No. FDA–2007–P–0300] (formerly 2007P–0326)''.

Dated: July 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17303 Filed 7–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0406]

Draft Information Sheet Guidance for Sponsors, Clinical Investigators, and Institutional Review Boards on Frequently Asked Questions—Statement of Investigator (Form FDA 1572); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft information sheet guidance entitled ''Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs; Frequently Asked Questions—Statement of Investigator (Form FDA 1572).'' This guidance is intended to assist institutional review boards (IRBs), clinical investigators, and sponsors involved in clinical investigations of investigational drugs and biologics in completing the Statement of Investigator form (Form FDA 1572). FDA developed this draft information sheet guidance in response to numerous questions from the research community regarding Form FDA 1572. This draft information sheet guidance provides FDA's responses to the most frequently asked questions.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft information sheet guidance by September 29, 2008.

ADDRESSES: Submit written comments on this draft information sheet guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft information sheet guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia M. Beers Block, Office of Science and Health Coordination/Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft information sheet guidance for sponsors, clinical investigators, and IRBs entitled ''Frequently Asked Questions—Statement of Investigator (Form FDA 1572).'' This guidance is intended to assist IRBs, clinical investigators, and sponsors involved in clinical investigations of investigational drugs and biologics in complying with the requirement that each investigator complete and sign a Form FDA 1572 before participating in an investigation. It describes how to complete the Statement of Investigator form (Form FDA 1572).

FDA developed this draft information sheet guidance in response to numerous questions from the research community regarding Form FDA 1572. In this draft guidance, we provide answers to frequently asked questions concerning the purpose of this form, when this form needs to be completed and signed by the investigator, how to best complete the various blocks within the form, and when the form might need to be updated. In addition, we clarify questions related to the use of Form FDA 1572 by clinical investigators participating in studies conducted outside the United States that may or may not be under an investigational new drug application.

This information sheet guidance is part of the Information Sheet Guidance Initiative announced in the **Federal Register** of February 3, 2006 (71 FR 5861), which describes FDA's intention to update the process for developing, issuing, and making available guidances intended for IRBs, clinical investigators, and sponsors. Known as ''Information Sheets,'' these guidances have provided recommendations to IRBs, clinical investigators, and sponsors to help them fulfill their responsibilities to protect human subjects who participate in research regulated by the FDA since the early 1980s. The Information Sheet Guidance Initiative is intended to ensure that the Information Sheets are consistent with the FDA's good guidance practices (GGPs). As part of the initiative, which will be ongoing, the agency plans to rescind Information Sheets that are obsolete, revise and reissue Information Sheet Guidances that address current issues, and develop new Information Sheet Guidances as needed.

This draft information sheet guidance is being issued consistent with FDA's GGPs regulation (21 CFR 10.115). The draft information sheet guidance, when finalized, will represent the agency's current thinking on completing Form FDA 1572. 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 statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information for Form FDA 1572 have been approved under OMB Control No. 0910–0014.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/oc/gcp/draft.html* or *http://www.regulations.gov*.

Dated: July 21, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17305 Filed 7–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0038]

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 10, 2008, from 8 a.m. to 5:45 p.m. and on September 11, 2008, from 8 a.m. to 3 p.m.

Location: Hilton Hotel, Washington, DC/Rockville Executive Meeting Center, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Donald W. Jehn or Pearline K. Muckelvene, Center for Biologics Evaluation and Research (CBER) (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014519516. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On the morning of September 10, 2008, the Committee will hear an update on the May 29 to 30, 2008, meeting of the Department of Health and Human Services Advisory Committee on Blood Safety and Availability. Following this update, the Committee will discuss strategies to enhance bacterial safety of 7 day platelets for transfusion. In the afternoon, the Committee will discuss iron status in blood donors. On September 11, 2008, the Committee will hear updates on the following topics: (1)