*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:**