We note that Mr. Bhutani has petitioned the U.S. Supreme Court for writ of certiorari of the Seventh Circuit's decision in his case. Should the outcome of further judicial proceeding result in Mr. Bhutani's conviction being reversed, under section 306(d)(3)(B)(i) of the act, the order of debarment will be withdrawn. Mr. Bhutani may file an application to terminate his debarment, under section 306(d)(4)(A) of the act. Any such application would be reviewed under the criteria and processes set forth in section 306(d)(4)(C) and (d)(4)(D) of the act. Such an application should be identified with Docket No. 2002N–0291 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(f). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 24, 2004.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–26532 Filed 12–1–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0493]

Draft Guidance for Industry on Recommended Approaches to Integration of Genetic Toxicology Study Results; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Recommended Approaches to Integration of Genetic Toxicology Study Results.'' This draft guidance is intended to inform industry on how the Center for Drug Evaluation and Research (CDER) views positive findings in genetic toxicology assays, and to provide recommendations to industry on how to proceed in assuring safety of healthy subjects or patients when results in genotoxicity studies suggest a potential cancer or genetic hazard.

DATES: Submit written or electronic comments on the draft guidance by January 31, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: David Jacobson-Kram, Center for Drug Evaluation and Research (HFD–024), Food and Drug Administration, 5515 Security Lane, Rockville, MD 20852, 301–443–5346.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Recommended Approaches to Integration of Genetic Toxicology Study Results.'' Risk for carcinogenesis is usually determined in rodent assays, in either 2–year studies or shorter-term studies using alternative models (ICH S1B). Regulatory decisions involving both single- and repeat-dose clinical studies are discussed in this guidance. Pharmaceuticals administered through oral, intravenous, topical, and other routes, as appropriate, are subject to this guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on recommended approaches to integration of genetic toxicology study results. 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. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, 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 draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: November 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26533 Filed 12–1–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; Longitudinal Investigation of Fertility and the Environment

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development, the National Institutes of Health has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register**, under the title ''Determinants of Male and Female Fecundity and Fertility,'' on January 9, 2004, page 1589 and allowed 60-days for public comment. Two public comments were received from the American Society for Reproductive Medicine and the American Chemistry Council Phthalate Esters Panel regarding specific aspects of the proposed methodology. Overall, comments from the former group pertained predominantly to clinical issues while the latter group's comments provided their rationale for the omission of phthalates from the protocol. These comments were useful in modifying the proposed study and instruments. The purpose of this notice is to allow an additional 30 days for public comment.

5 CFR 1320.5 (General Requirements) Reporting and Recordkeeping

Requirements: Final Rule requires that the agency inform the potential