

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0279]

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Certifier A. Corbin

**Developing Drug Information Association/Food and Drug Administration  
Workshop: Pharmacogenomic Combination Product Co-Development;  
Public Meeting**

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

**ACTION:** Notice of public meeting; request for comments.

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**SUMMARY:** The Food and Drug Administration (FDA), in cooperation with the Drug Information Association (DIA), is announcing a public meeting to solicit views and to provide an interactive forum for discussion of industry and other perspectives and experience derived from the development of recently approved pharmacogenomic combination products. The input received at the meeting, comments received during the meeting, and comments made to the docket after the meeting, may be considered in developing a draft guidance on this topic.

**DATES:** The public meeting will be held on July 29, 2004, from 8 a.m. to 5:30 p.m. Attendees must register to attend. Submit written or electronic requests to speak at the public meeting by July 26, 2004. Submit written or electronic comments before or after the meeting by August 30, 2004.

**ADDRESSES:** The public meeting will be held at the Marriott Crystal Gateway Hotel, 1700 Jefferson Davis Hwy., Arlington, VA. A copy of the meeting's program is available on the Internet at <http://www.diahome.org/Content/Events/04040.pdf>.

Submit written comments 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>.

**FOR FURTHER INFORMATION CONTACT:**

*Those wishing to speak should contact:* Allen Rudman, Office of Clinical Pharmacology and Biopharmaceutics, Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7691, e-mail: [RUDMANA@CDER.FDA.GOV](mailto:RUDMANA@CDER.FDA.GOV).

*Those wishing to register for the meeting should contact:* Drug Information Association, P.O. Box 827192, Philadelphia, PA 19182-7192, e-mail: [DIA@DIAHOME.ORG](mailto:DIA@DIAHOME.ORG).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is embarking on a new initiative to develop guidance for the codevelopment of pharmacogenomic-based therapeutic drug and biological products and the diagnostic tests that are necessary for therapeutic decision making. A number of diagnostic tests could be developed for use with drug or biological products including, for example, tests related to treatment decisions, such as whether patients should be treated, the dose used for treatment, or to identify the risks associated with treatment. FDA expects to develop guidance for the codevelopment of therapeutic and diagnostic products where both will be necessary in the clinical management of patients.

In preparation for drafting the guidance, FDA and DIA have planned a 1-day mini-meeting, in collaboration with Pharmaceutical Research and Manufacturers of America, Biotechnology Industry Organization, Advanced

Medical Technology Association, Medical Device Manufacturers Association, the DIA Biotechnology Special Interest Action Committee, and the Pharmacogenomics Working Group, to identify important issues related to the codevelopment of pharmacogenomic combination products. FDA believes it is important to receive input from industry and other interested parties through a public meeting before drafting the guidance.

Previously, FDA and industry have cosponsored two multi-day meetings on pharmacogenomics in May 2002 and November 2003, respectively. This collaboration between industry, FDA, and other interested parties has also facilitated the writing and issuance of the draft guidance for industry entitled "Pharmacogenomic Data Submissions," which was issued in November 2003 and is currently being finalized.

## **II. Goals of the Meeting**

The primary intent of this mini-meeting is to provide an interactive forum for discussing industry and other perspectives and experience derived from the development of recently approved pharmacogenomic combination products. This meeting is intended to be highly interactive, identify issues, and address questions that will provide FDA with valuable information to consider during development of guidance for industry on the codevelopment of pharmacogenomic combination products for therapeutic and diagnostic use.

Key areas identified for particular focus include the following:

- Industry vision of an ideal codevelopment process and regulatory framework,
- Clinical trial design and statistical challenges for the codevelopment of therapeutic and diagnostic pharmacogenomic products,
- Case studies to explore detailed considerations for the analytical validation of pharmacogenomic diagnostic products, and

- Clinical utility of pharmacogenomic diagnostic products.

Specific goals of the meeting include the following:

1. Provide greater awareness and understanding of the regulatory and scientific challenges of codeveloping pharmacogenomic combination products.
2. Obtain greater clarity on the clinical and statistical design issues that affect the codevelopment of drug and pharmacogenomic combination products.
3. Provide an opportunity to help define the elements that are needed in guidance for industry to enhance the codevelopment of pharmacogenomic combination products.
4. Provide pharmaceutical, biological product, device industries, and other public stakeholders with an opportunity to identify issues and propose recommendations for FDA consideration as it develops formal guidance on the codevelopment of pharmacogenomic combination products.

### **III. Intended Audience**

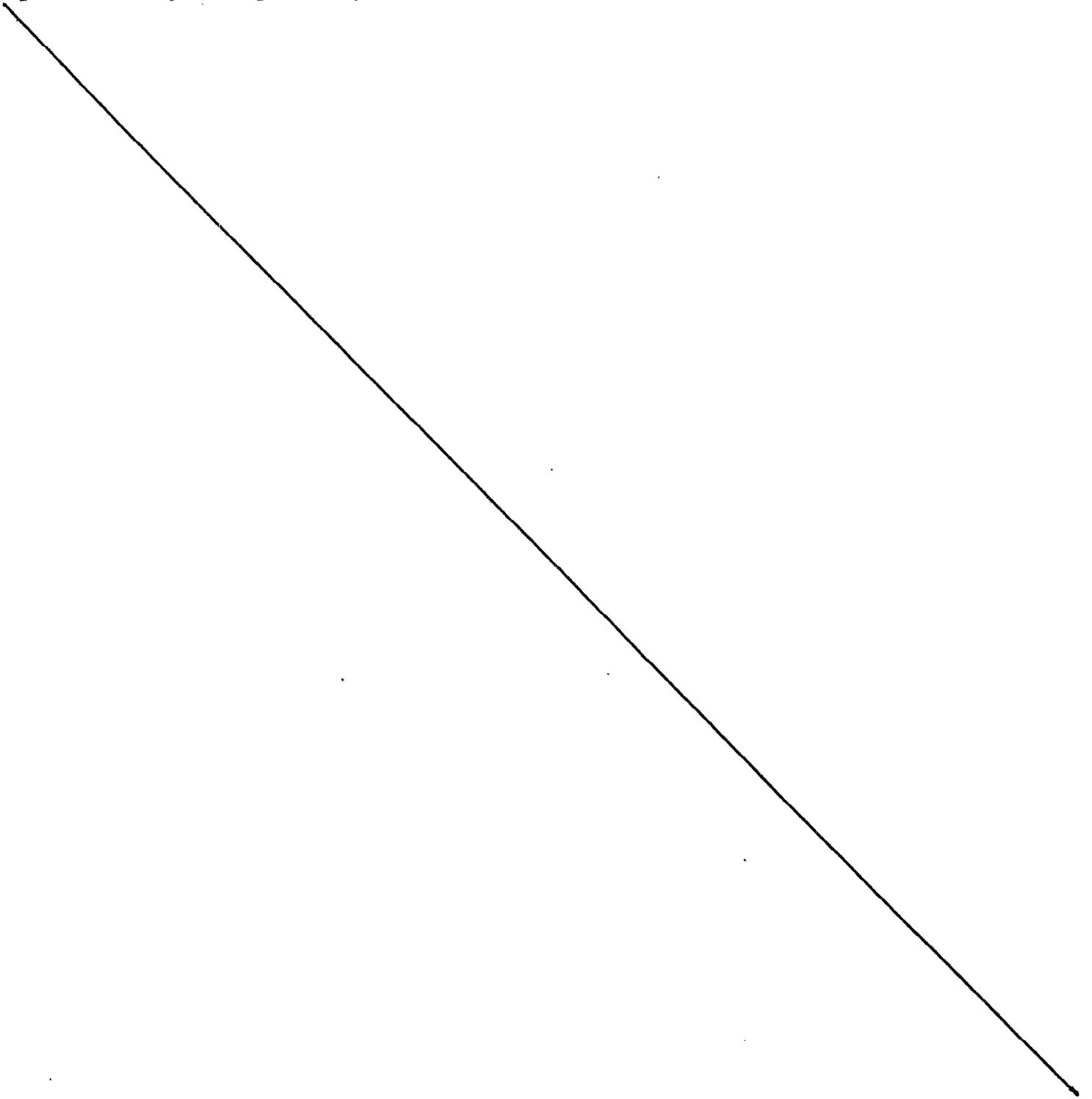
This meeting is intended for developers and potential developers of therapeutic drug and biological products and pharmacogenomic-based diagnostic products to be developed and approved with them as combination products. Other interested persons may include regulatory/clinical decision-makers, designers of clinical and laboratory validation protocols, clinical pharmacologists, physicians, biostatisticians, and geneticists working in industry or academia.

### **IV. Request for Comments**

Regardless of attendance at the meeting, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the topics presented in this document. The agency welcomes comments before and after the meeting. 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. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.



Dated: 7-8-04  
July 8, 2004.

cd0479

*Jeffrey Shuren*

Jeffrey Shuren,  
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