Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of September 13, 2004 (69 FR 55163), FDA published a notice announcing the availability of a draft tripartite guidance entitled ''E14 Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs.'' The notice gave interested persons an opportunity to submit comments by December 13, 2004. In response to a request for additional time to comment, FDA reopened the comment period until February 18, 2005 (70 FR 823, January 5, 2005). On April 11 and 12, 2005, FDA, the Drug Information Association, and the Heart Rhythm Society cosponsored a public meeting to discuss the draft guidance. Comments received at the meeting were made available to the Efficacy Expert Working Group. After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in May 2005.

The guidance provides guidance on the design, conduct, analysis and interpretation of clinical studies to assess the potential of a new drug to cause cardiac arrhythmias, focusing on the assessment of changes in the QT/QTc interval on the electrocardiogram as a predictor of risk. The guidance is intended to encourage the assessment of drug effects on the QT/QTc interval, along with the collection of adverse cardiac events related to arrhythmias, as a standard part of drug development, and to encourage the early discussion of this assessment with the FDA. The goal of such discussions is to reach a common understanding of the effects as early in development as practical, with the goal of enhancing the efficiency of data collection later in drug development. The guidance incorporates the following changes: (1) A fuller discussion of the factors that influence the clinical assessment of drug effects on the QT interval and (2) an adjustment in the statistical analysis of QT interval data obtained as a part of early thorough QT assessment.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. 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 guidance at anytime. 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.

III. Electronic Access

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

Dated: October 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20971 Filed 10–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0362]

Draft Guidance for Industry on Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin Antibodies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies,'' dated October 2005. The draft guidance document is intended to assist source plasma manufacturers in submitting to FDA the appropriate information when implementing an IgG antibody collection program or when adding a new IgG antibody collection to an existing program. The draft guidance, when finalized, would supersede the draft reviewers' guide entitled ''Disease Associated Antibody Collection Program,'' dated October 1, 1995.

DATES: Submit written or electronic comments on the draft guidance by January 18, 2006 to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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*.

FOR FURTHER INFORMATION CONTACT: Brenda R. Friend, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Recommendations for Implementing a Collection Program for Source Plasma Containing Disease-Associated and Other Immunoglobulin (IgG) Antibodies'' dated October 2005. The draft guidance, when finalized, would supersede the draft reviewers' guide, ''Disease Associated Antibody Collection Program,'' dated October 1, 1995. The document provides guidance to source plasma manufacturers in submitting the appropriate information to FDA when implementing an IgG antibody collection program or when adding a new IgG antibody collection to an existing program. The guidance identifies changes in collection programs that must be documented as minor changes in an annual report to FDA under § 601.12(d) (21 CFR 601.12(d)). These collection programs include disease-associated IgG

antibodies and other existing IgG antibodies. The guidance also identifies labeling changes to be submitted as a supplement for changes being effected under § 601.12(f)(2)(i)(E). The guidance neither includes recommendations related to implementing Immunoglobulin M antibody collection programs, nor does it include recommendations for donors who do not meet all donor suitability requirements under 21 CFR 640.63.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 collection(s) of information in this guidance was approved under OMB control number 0910–0338.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. 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 the brackets in the heading of this document. A copy of 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.

IV. Electronic Access

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

Dated: October 12, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–20958 Filed 10–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: September 2005

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of September 2005, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject name	Address	Effective date
Program-Related Convictions:		
Agopian, Ovsanna	Granada Hills, CA	10/20/2005
Altidor, Rejeanne	Elmont, NY	10/20/2005
Andino, Rosario	Miami, FL	10/20/2005
Arnold, David	Athens, PA	10/20/2005
Arthur Avenue Pharmacy	Bronx, NY	10/20/2005
Bagley, Barbara	Los Angeles, CA	10/20/2005
Barragan, Elian	Bronx, NY	10/20/2005
Barrett, Nadine	Bronx, NY	10/20/2005
Blumberg, Gary	Deerfield, FL	10/20/2005
Brailsford, Philip	Escondido, CA	10/20/2005
Brown, Roger	Trenton, NJ	10/20/2005
Burleson, Delpha	Purcell, OK	10/20/2005
Butts, Frank	Texarkana, TX	10/20/2005
Cansler, Ronnie	Los Angeles, CA	10/20/2005
Cardio Diagnostic Technology & Consultants, Inc	Westerville, OH	10/20/2005
Celestin, Andre	Elmont, NY	10/20/2005
Central Community Service, Inc	Los Angeles, CA	10/20/2005
Chaffin, Alisa	Lansing, MI	10/20/2005
Choi, Ricardo	Miami, FL	10/20/2005
Cifelli, Charles	The Villages, FL	10/20/2005
Cifelli, Darren	West Yarmouth, MA	10/20/2005
Cifelli, Karen	West Yarmouth, MA	10/20/2005
Clark, Harry	Pensacola, FL	10/20/2005
Clark, Shirley	Vallejo, CA	10/20/2005
Collins, Monique	New Orleans, LA	10/20/2005
Davidson, Lee	Los Angeles, CA	10/20/2005
Davis, James	Irving, TX	10/20/2005
Du, Danny	Wasco, CA	10/20/2005
Estevez, Maria	Coleman, FL	10/20/2005
Fabian, Misty	Timpson, TX	10/20/2005
Flanigan, George	Los Angeles, CA	10/20/2005
Flores, William	Los Angeles, CA	10/20/2005