four-of-a-kind rule for use of data in PMA's. Under the four-of-a-kind rule, the agency could use data contained in any filed PMA 1 year after FDA had approved the fourth device of a kind. The four-of-a-kind provision also contained detailed rules for its application to data in applications approved before the SMDA's effective date. The SMDA provision replaced section 520(h)(3) of the act, which was enacted with the Medical Device Amendments of 1976 (MDA). Under the MDA, the agency could not use data in one PMA to establish the safety or effectiveness of any device other than the one for which the data was submitted.

FDA is issuing this guidance in response to conflicting interpretations of section 216 of FDAMA advanced by regulated industry. FDA has concluded that it will apply section 216 to free data only in PMA's approved after November 28, 1990, the date of enactment of the SMDA. The agency does not intend to use data in PMA's approved before that date other than data that would be available to FDA without the authority granted by section 216 of FDAMA, such as published studies. The guidance also sets forth procedures for identifying and using data available under section 216 of FDAMA.

II. Significance of Guidance

This guidance document represents the agency's current thinking on section 216 of FDAMA. 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 applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is being issued as a Level 1 guidance consistent with GGP's. This guidance document is effective immediately because it interprets a new statutory requirement that has been in effect since February 19, 1998.

III. Electronic Access

In order to receive ''Guidance for Industry and for FDA Reviewers: Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997,'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system and enter the document number (1135) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes, ''Guidance for Industry and for FDA Reviewers: Guidance on Section 216 of the Food and Drug Administration Modernization Act of 1997,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this immediately-in-effect guidance by November 7, 2000. Submit to the contact person (address above) written comments regarding this guidance after November 7, 2000. Such comments will be considered when determining whether to amend the current guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 27, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–20088 Filed 8–8–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1408]

International Conference on Harmonisation; Draft Guidance on Principles for Clinical Evaluation of New Antihypertensive Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''E12A Principles for Clinical Evaluation of New Antihypertensive Drugs.'' The draft guidance, prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), was designated an ICH principle document. The draft guidance is intended to provide general principles for the clinical evaluation of new antihypertensive drugs. It describes the core principles accepted in the three ICH regions for the evaluation of new antihypertensive drugs, including assessments of efficacy and safety and choice of study population.

DATES: Submit written comments on the draft guidance by November 7, 2000.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Copies of the draft guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/publications.htm. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist the office in processing your requests. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Robert Temple, Center for Drug Evaluation and Research (HFD–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758.

Regarding the ICH: Janet J. Showalter, Office of International Programs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0864.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of

regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug and biological product development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industries Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA, and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International 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, the Canadian Health Protection Branch, and the European Free Trade Area.

To facilitate the process of making ICH guidances available to the public, the agency is changing its procedures for publishing ICH guidances. Beginning April 2000, we will follow the same procedures we follow with other agency guidances. Rather than including the text of ICH guidances in the **Federal Register**, we will publish a notice in the **Federal Register** announcing the availability of an ICH guidance. The ICH guidance will be placed in the docket and can be obtained through regular agency sources (see the **ADDRESSES** section). The draft guidance will be left in the original ICH format. The final guidance will be reformatted to conform to GGP style before publication.

In March 2000, the ICH Steering Committee agreed that a draft guidance entitled ''E12A Principles for Clinical Evaluation of New Antihypertensive Drugs'' should be made available for public comment. The draft guidance, which is the product of the Efficacy Expert Working Group of the ICH, was designated an ICH principle document. Because requirements of the three ICH regions differ in some specifics, this ICH principle document will not be subject to the usual ICH step procedures leading to a fully harmonized document. Comments about this draft will be forwarded to the three regulatory parties for consideration.

In accordance with FDA's good guidance practices (GGP's)(62 FR 8961, February 27, 1997), this document is being called a guidance, rather than a principle document.

The draft guidance is intended to provide general principles for the clinical evaluation of new antihypertensive drugs. It describes core principles that are accepted in the three ICH regions for the evaluation of antihypertensives, including assessments of efficacy and safety and choice of study population. The draft guidance is meant to be used together with other ICH clinical guidances.

This draft guidance represents the agency's current thinking on the clinical evaluation of new antihypertensive drugs. 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, regulations, or both.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance by November 7, 2000. Two copies of any comments are to be submitted, except that individuals may submit one 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 2, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–20172 Filed 8–8–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Methods for Reducing Tumor Growth and Metastasis by Inhibiting MCP–1 Activity

WJ Murphy, JJ Oppenheim, and R Salcedo (all of NCI)
Serial No. 60/205,757 filed 19 May 2000
Licensing Contact: Susan S. Rucker; 301/496–7056 ext. 245; e-mail: ruckers@od.nih.gov

This application relates to methods for the inhibition of tumor growth and metastasis. The inhibition of tumor growth and metastasis is based on the demonstration that certain inhibitors of the chemokine MCP–1 (monocyte chemotactic protein 1 also known as JE) inhibit angiogenesis in *in vitro* and *in vivo* model systems. In addition, methods for identifying other inhibitors are described. In addition to this application the NIH has other intellectual property related to MCP–1 which is available for license, including U.S. Patents 5,714,578, 5,532,144, 5,179,078, 5,212,073 and 5,278,287.

This work has been published, in part in Blood 96(1): July 1, 2000.

The Use of an Inducible Plasmid Vector Encoding for Active TGF–β for the Treatment of Autoimmune Diseases

A Kitani, I Fuss, K Nakamura and W Strober(NIAID)
DHHS Reference No. E–096–00/0 filed 20 Apr 2000
Licensing Contact: Susan S. Rucker; 301/496–7056 ext. 245; e-mail: ruckers@od.nih.gov

This application describes a composition and method for treating inflammatory bowel disease or other autoimmune diseases. The composition utilizes a vector which contains a first