• Twelve-month studies may be more appropriate for new molecular entities acting at new molecular targets where postmarketing experience is not available for the pharmacological class. Thus, the therapeutic is the first in a pharmacological class for which there is limited human or animal experience on its long-term toxic potential.

As with all of FDA's guidances, the public is encouraged to submit written comments with new data or other new information pertinent to this guidance. The comments in the docket will be periodically reviewed, and, where appropriate, the guidance will be amended. The public will be notified of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). 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 and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. An electronic version of this guidance is available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or at CBER's World Wide Web site at ''http://www.fda.gov/cber/publications.htm''.

The text of the guidance follows:

S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)[1]

1. Objective

The objective of this guidance is to set out the considerations that apply to chronic toxicity testing in rodents and nonrodents as part of the safety evaluation of a medicinal product. Since guidance is not legally binding, an applicant may submit justification for an alternative approach.

2. Scope

This guidance has been prepared for the development of medicinal products with the exception of those already covered by the ICH guidance ''S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals'' (62 FR 61515, November 18, 1997), e.g., monoclonal antibodies, recombinant DNA proteins.

3. Background

During the first International Conference on Harmonisation in 1991, the practices for the testing of chronic toxicity in the three regions (the European Union, Japan, and the United States) were reviewed. Arising from this, it emerged that there was a scientific consensus on the approach for chronic testing in rodents, supporting the harmonized duration of testing of 6 months. However, for chronic toxicity testing in nonrodents, there were different approaches to the duration of testing.

The lack of harmonized duration led to the need for pharmaceutical companies to perform partially duplicative studies for both 6 and 12 months' duration when developing new medicinal products. As the objective of ICH is to reduce or eliminate the need to duplicate testing during development of medicinal products and to ensure a more economical use of material, animal, and human resources, while at the same time maintaining safeguards to protect public health, further scientific evaluation was undertaken.

Each of the regulatory authorities in the European Union, Japan, and the United States undertook a review to determine whether a single duration for chronic toxicity testing in nonrodents could be identified. From this analysis, it emerged that in 16 cases a more detailed evaluation of 6 versus 12 months' data should be undertaken.

This evaluation was conducted as a joint exercise by the competent authorities in the three regions.

In some of the cases analyzed at the tripartite meetings, there were no additional findings at 12 months. For some other cases, there was not complete agreement among the regulators with respect to the comparability in study design and conduct to allow assessment of whether there were differences in the findings at 6 and 12 months due to duration of treatment alone.

In a number of cases there were findings observed by 12 months, but not by 6 months. It was concluded that these would, or could, have been detected in a study of 9 months' duration. Varying degrees of concern for the differences in findings detected between the studies of different durations were expressed. An agreement on the clinical relevance of these findings could not be reached.

Studies of 12 months' duration are usually not necessary, and studies of shorter than 9 months' duration may be sufficient.

In the European Union, studies of 6 months' duration in nonrodents are acceptable according to Council Directive 75/318/EEC, as amended. To avoid duplication, where studies with a longer duration have been conducted, it would not be necessary to conduct a study of 6 months.

4. Guidance on Duration of Chronic Toxicity Testing for Tripartite Development Plan

Arising from the extensive analysis and review of the above mentioned data in nonrodents and based upon the achievements of ICH 1 for testing in rodents, and so as to avoid duplication and follow a single development plan for chronic toxicity testing of new medicinal products, the following studies are considered acceptable for submission in the three regions:

(1) *Rodents*:A study of 6 months' duration;

(2) *Nonrodents*: A study of 9 months' duration.

[1] This guidance represents the agency's current thinking on the duration of chronic toxicity testing in animals (rodent and nonrodent toxicity testing). 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 satisifes the requirements of the applicable statute, regulations, or both.

Dated: June 17, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy Coordination.

[FR Doc. 99–16189 Filed 6–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Donor Suitability Workshop: Donor History of Hepatitis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop entitled ''Blood Donor Suitability Workshop: Donor History of Hepatitis.'' The purpose of the workshop is to discuss whether prospective blood donors with a history of viral hepatitis should be deferred from donating blood.

Date and Time: The workshop will be held on Wednesday, July 21, 1999, 8:30 a.m. to 5 p.m.

Location: The workshop will be held at Natcher Auditorium, Bldg. 45, 45 Center Dr., National Institutes of Health, 8800 Rockville Pike, Bethesda, MD.

Contact: Joseph Wilczek, Center for Biologics Evaluation and Research (HFM–350), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6129, FAX 301–827–2843.

Registration: Early registration is recommended. Mail or fax registration information (including name, title, firm name, address, telephone, and fax number), to the contact person on or before Friday, July 2, 1999.

Registration at the site will be done on a space available basis on the day of the workshop beginning at 7:30 a.m. There is no registration fee for the workshop.

If you need special accommodations due to disability, please contact Joseph Wilczek at least 7 days in advance.

Agenda: The public workshop is intended to discuss a variety of issues concerning blood donor deferrals based on a history of viral hepatitis. These issues include, but are not limited to, the following: (1) Definitions and clarification of terms such as ''history of hepatitis'' and ''history of jaundice'' in the context of blood donation; (2) whether a prospective blood donor with a history of hepatitis A, who is anti-HAV IgG positive, is an unacceptable donor; (3) whether deferrals are appropriate for individuals with a

history of viral hepatitis that was documented to be due to some other virus other than hepatitis A through G; and (4) whether a history of hepatitis in the absence of positive viral marker tests for hepatitis preclude blood donations.

Transcripts: Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 days after the workshop at a cost of 10 cents per page. The workshop transcript will also be available on the Center for Biologics Evaluation and Research website at ''http://www.fda.gov/cber/minutes/workshop-min.htm''.

Dated: June 18, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–16147 Filed 6–24–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Electric and Magnetic Fields Research and Public Information Dissemination Program (EMFRAPID Program)

AGENCY: Environmental Toxicology Program, Office of Special Programs, National Institute of Environmental Health Sciences, National Institutes of Health.

Notice: Release of NIEHS Report on Electric and Magnetic Fields.

Background

The National Institute of Environmental Health Sciences (NIEHS) and the Department of Energy (DOE) coordinated implementation of the Electric and Magnetic Fields Research and Public Information Dissemination Program (EMF*RAPID* Program). This six-year program was mandated in the 1992 Energy Policy Act (PL 102–486, section 2118) and is designed to determine the potential effects on human disease from exposure to 60 Hz electric and magnetic fields (EMF). These fields are invisible lines of force that surround any wire or device that uses electricity. Additional details about the EMF*RAPID* Program are found in **Federal Register,** December 16, 1997 (Volume 62, No. 241, pp. 65814–65815).

Under this program, the NIEHS conducted a two-year review and analysis of the existing scientific data on EMF and prepared a report for the U.S. Congress that contains its conclusions from the health assessment. This assessment included an evaluation of the evidence by scientists both within and outside the field of EMF research as well as an opportunity for public comment through sponsorship of public meetings and solicitation written comments. The NIEHS report was released on June 15, 1999 and is available free-of-charge to the public and other interested parties.

The report is available in both PDF and HTML formats at the EMF*RAPID* Program world wide website, www.niehs.nih.gov/emfrapid/home.htm. Copies of the report can also be obtained by sending a request by fax: 919–541–0144 or mail: EMF–RAPID Program, NIEHS/NIH, P.O. Box 12233 MD EC–16, Research Triangle Park, NC 27709; or by calling 919–541–7534.

Dated: June 18, 1999.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. 99–16255 Filed 6–24–99; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Treatment Outcomes and Performance Pilot Studies (TOPPS)—(OMB No. 0930–0182; Extension)

The TOPPS program awarded contracts to 14 States to develop and pilot test performance and outcomes measures for substance abuse treatment services. The pilot studies are collecting data from substance abuse clients, including pregnant women, women with dependent children, adolescents, and managed care clients. Measures of addiction severity and other outcomes are being obtained at admission, discharge and post-discharge. These States were granted OMB clearance on data collection until September 30, 1999. SAMHSA is requesting an extension of OMB approval for one of these States, Utah, to allow them to complete data collection. The estimated burden for this extension is summarized below.

	Number of respondents	Responses/respondent	Average burden/ response (hrs.)	Annualized total burden (hrs.)
All States, currently approved (includes Utah)	(6,419)	2.0	.51	(6,551)
Utah—extension	420	2.9	.20	246
Revised Total	420			246