minimum requirements specified by the Secretary and to give full faith and credit to such an affidavit signed in any other State according to its procedures. The Department established a task group composed of Federal and State staff to recommend minimum data elements for all State paternity acknowledgment affidavits. The minimum data elements were crafted to balance the need for a tool for collecting information necessary to the establishment of a child support order and the need for a user-friendly form that addresses only the data necessary to establish legal paternity. *The minimum data elements are:* The current full name, social security number and date of birth of mother, father, and child; address of mother and father, birthplace of child; an explanation of the legal consequences of signing the affidavit; a statement indicating both parents understand their rights, responsibilities, alternatives and the consequences of signing the affidavit; the place the affidavit was completed; and signature lines for mother, father and witnesses or notaries.

Respondents: Individuals and Households; Not-for-Profit Institutions; and State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Affidavits	2,000,000	.2243	.166	74,468

Estimated Total Annual Burden Hours: 74,468.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: November 12, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–30220 Filed 11–17–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0444]

International Conference on Harmonisation; Draft Guidance on the Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft guidance entitled ''S4A Duration of Chronic Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing).'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance is intended to provide guidance on the duration of chronic toxicity testing in rodents and nonrodents as part of the safety evaluation of a drug product.

DATES: Written comments by January 20, 1998.

ADDRESSES: Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the draft guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6758.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (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 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.

In July 1997, the ICH Steering Committee agreed that a draft guidance entitled ''S4A Duration of Chronic

Toxicity Testing in Animals (Rodent and Nonrodent Toxicity Testing)'' should be made available for public comment. The draft guidance is the product of the Safety Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Safety Expert Working Group.

In accordance with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997), this document has been designated a guidance, rather than a guideline.

The draft document provides guidance on the duration of chronic toxicity testing in rodents and nonrodents as part of the safety evaluation of a drug product. The draft guidance is intended to help eliminate or reduce the need for pharmaceutical companies to duplicate testing during the development of new drug products.

FDA has proposed draft guidance before on chronic toxicity testing. In the **Federal Register** of April 15, 1992 (57 FR 13105), FDA announced the availability of a proposed approach to toxicity testing, including long-term toxicity studies. The new ICH draft guidance published here reflects a change in recommended testing in nonrodents based on an evaluation of findings from chronic toxicity studies. The evaluation report is available in Docket No. 97D–0444. The agency requests comments on the draft guidance and on specific classes of pharmaceuticals for which either shorter or longer durations of testing in nonrodents should be considered as general exceptions to the duration recommended in the draft guidance. It would be helpful if the scientific basis for comments addressing ''general exceptions'' were also provided. Once this guidance is finalized, it will supersede the 1992 proposed guidance (57 FR 13105).

Other portions of the proposed approach to toxicity testing announced in the **Federal Register** of April 15, 1992, have been superseded by draft and finalized FDA and ICH guidances as follows:

TABLE 1.—1992 DRAFT PROPOSED GUIDANCE

Topic	Superseded by
Single Dose (Acute) Toxicity Studies	Guidance for Industry on Single Dose Acute Toxicity Testing for Pharmaceuticals, PT 1, (61 FR 43934, August 26, 1996)
Reproductive and Developmental Studies	Detection of Toxicity to Reproduction for Medicinal Products, ICH S5A, (59 FR 48746, September 22, 1994)
	Detection of Toxicity to Reproduction for Medicinal Products: Addendum on Toxicity to Male Fertility, ICH S5B (61 FR 15360, April 5, 1996)
Carcinogenicity Studies (Dose Selection)	Dose Selection for Carcinogenicity Studies of Pharmaceuticals, ICH S1C, (60 FR 11278, March 1, 1995)
	Dose Selection for Carcinogenicity Studies of Pharmaceuticals—Addition of the Limit Dose and Related Notes, Draft ICH S1C(R) (62 FR 15715, April 2, 1997)
Timing and Duration	Nonclinical Studies for the Conduct of Human Clinical Trials for Pharmaceuticals, Draft ICH M3 (62 FR 24320, May 2, 1997)

This draft 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 satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, on or before January 20, 1998, submit to the Dockets Management Branch (address above) written comments on the draft 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 draft 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 using the World Wide Web (WWW) ''http://www.fda.gov/cder/guidance.htm''.

The text of the draft guidance follows:

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

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.

Scope:

This guidance has been prepared for the development of medicinal products with the exception of those already covered by ''Safety Studies for Biotechnological Products,'' e.g., monoclonal antibodies, recombinant DNA proteins.

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.

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 to 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.

Dated: November 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–30273 Filed 11–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0113]

International Conference on Harmonisation; Guidance on Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a guidance entitled ''S6 Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance is intended to provide general principles for designing scientifically acceptable preclinical safety evaluation programs for biopharmaceuticals.

DATES: Effective November 18, 1997. Submit written comments at any time.

ADDRESSES: Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Copies of the guidance are available from the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4573. Single copies of the draft guidance may be obtained by mail from the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), or by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. Copies may be obtained from CBER's Fax Information System at 1–888–CBER–FAX or 301–827–3844.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Joy A. Cavagnaro, Center for Biologics Evaluation and Research (HFM–5), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0379.

Regarding the ICH: Janet J. Showalter, Office of Health Affairs (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 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.

In the **Federal Register** of April 4, 1997 (62 FR 16438), FDA published a draft tripartite guideline entitled ''Preclinical Testing of Biotechnology-Derived Pharmaceuticals'' (S6). The notice gave interested persons an opportunity to submit comments by June 3, 1997.

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 on July 16, 1997.

In accordance with FDA's Good Guidance Practices (62 FR 8961, February 27, 1997), this document has been designated a guidance, rather than a guideline.

The guidance recommends a basic framework for the preclinical safety evaluation of biotechnology-derived pharmaceuticals. Adherence to the principles presented in the guidance will allow for improvement in the quality and consistency of preclinical safety data supporting the development of biopharmaceuticals.

This guidance represents the agency's current thinking on preclinical safety evaluation of biotechnology-derived pharmaceuticals. 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 statute, regulations, or both.

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**.