

Dated: July 26, 2000.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1425]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Tissue Intended for Transplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to FDA regulations for human tissue intended for transplantation.

DATES: Submit written comments on the collection of information by October 6, 2000.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency request

or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Human Tissue Intended for Transplantation—Part 1270 (21 CFR Part 1270)—(OMB Control Number 0910-0302)—Extension

Under section 361 of the Public Health Service Act (42 U.S.C. 264), FDA issued regulations to prevent the transmission of human immunodeficiency virus (HIV), hepatitis B, hepatitis C, and other organisms causing infectious disease through the use of human tissue for transplantation. The regulations provide for inspection by FDA of persons and tissue establishments engaged in the recovery, screening, testing, processing, storage, or distribution of human tissue. These facilities are required to meet standards intended to ensure appropriate screening and testing of human tissue donors and to ensure that records are kept documenting that the appropriate screening and testing have been completed.

Section 1270.31(a) and (b) require written procedures to be prepared and followed for: (1) All significant steps in the infectious disease testing process, and (2) all significant steps in determining the medical history of the donor. Any deviation from the written procedures are to be recorded and justified. Section 1270.33(a) requires records to be maintained concurrently

with the performance of each significant step in the procedures of infectious disease screening and testing of human tissue donors. Section 1270.33(f) requires records be retained regarding the determination of the suitability of the donors and such records required under § 1270.21. Section 1270.33(h) requires all records be retained at least 10 years beyond the date of transplantation, distribution, disposition, or expiration, of the tissue, whichever is latest. Section 1270.35 requires specific records to be maintained to document: (1) The results and interpretation of all required infectious disease tests and results, (2) the identity and relevant medical records of the donor, (3) the receipt and distribution of human tissue, and (4) the destruction or other disposition of human tissue.

Respondents to this collection of information are manufacturers of human tissue-based products. Based on information provided by industry associations, there are approximately 224 manufacturers of conventional tissue and eye tissue. An estimated total of 309,000 conventional tissue products and 86,000 eye tissue products are manufactured per year. There are an estimated 6,500 donors of conventional tissue and 43,300 donors of eye tissue each year, with an estimated 12,900 unsuitable donors. In estimating the burden, FDA compared the agency regulations with the current voluntary standards of a number of industry organizations, such as the American Association of Tissue Banks and the Eye Bank Association of America. In those cases where a voluntary industry standard appears to be equivalent to the agency regulation, FDA has assumed that any recordkeeping burden would continue as customary and usual business practice of an establishment that are members of those organizations and therefore no additional burden is calculated. To account for establishments that may not be a member of an industry organization and would not perform these provisions as customary and usual practice, FDA is using 1 percent of the number of recordkeepers and total annual records as an estimation of the information collection burden on the tissue industry. The requirement for written procedures is considered a one-time burden, therefore, the information collection burden under § 1270.31(a) and (b) is for the recording and justifying of any deviations from the written procedures. The information collection burden for the regulation under § 1270.33 is being calculated with § 1270.35(a) because it

would be duplicating burden and difficult to calculate separately. The following recordkeeping estimates for the number of recordkeepers, total

annual records, and hours per record are based on information provided by industry, and FDA experience.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1270.31(a) and 1270.31(b)	2	2	4	1.0	4
1270.33(a), (f), and (h), and 1270.35(a) and (b)	2	498	996	1.0	996
1270.35(c)	2	1,975	3,950	1.0	3,950
1270.35(d)	2	65	130	1.0	130
Total					5,080

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 28, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D-1407]

International Conference on Harmonisation; Draft Guidance on Safety Pharmacology Studies for Human Pharmaceuticals; 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 "S7 Safety Pharmacology Studies for Human Pharmaceuticals." 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 describes general principles and recommendations for safety pharmacology evaluations. The draft guidance is intended to help protect clinical trial participants and patients receiving marketed products from potential adverse reactions to pharmaceuticals and to avoid unnecessary use of animals and other resources.

DATES: Submit written comments on the draft guidance by September 6, 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.

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, 301-594-5476.

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 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 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 guideline.

To facilitate the process of making ICH guidances available to the public, the agency is changing its procedure for publishing ICH guidances. Beginning April 2000, we will no longer include the text of ICH guidances in the **Federal Register**. Instead, 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.