

both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 25, 2003.

**Alvin Hall,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0404]

#### 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 or electronic comments on the collection of information by December 1, 2003.

**ADDRESSES:** Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (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:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**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 requests 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 these topics: (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—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, and hepatitis C, 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 provisions 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) through (d) (21 CFR 1270.31(a) through (d)) require written procedures to be prepared and followed for the following steps: (1) All significant steps in the infectious disease testing process, (2) all

significant steps in reviewing the relevant medical record of the donor, (3) designating and identifying quarantined tissue, and (4) for prevention of infectious disease contamination or cross-contamination by tissue during processing. Section 1270.31(a) and (b) also require recording and justification of any deviation from the written procedures. Section 1270.33(a) (21 CFR 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 to be retained regarding the determination of the suitability of the donors and such records required under § 1270.21 (21 CFR 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 (21 CFR 1270.35) requires specific records be maintained to document the following outcomes: (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 intended for transplantation. Based on information from FDA's Center for Biologics and Evaluation Research database system, the agency estimates that there are approximately 300 tissue establishments of which 166 are conventional tissue banks and 134 are eye tissue banks. Based on information provided by industry, there are an estimated total of 750,000 conventional tissue products and 94,186 eye tissue products recovered per year with an average of 25 percent of the tissue discarded due to unsuitability for transplant. In addition, there are an estimated 20,000 donors of conventional tissue and 47,796 donors of eye tissue each year.

Accredited members of the American Association of Tissue Banks (AATB) and Eye Bank Association of America (EBAA) adhere to standards of those organizations that are comparable to the recordkeeping requirement in part 1270 (21 CFR part 1270). Based on information provided by industry associations, 50 to 75 percent (average 63 percent) of the conventional tissue banks are members of AATB (166 X 63 percent = 105), and 99 percent of eye tissue banks are members of EBAA (134 X 99 percent = 133). Therefore, recordkeeping by these 238

establishments (105 + 133 = 238) is excluded from the burden estimates as usual and customary business activities (5 CFR 1320.3(b)(2)). The recordkeeping burden, thus, is estimated for the remaining 62 establishments, which is 21 percent of all establishments (300 - 238 = 62, or 62/300 = 21 percent).

Based on CBER's database system and information provided by industry, FDA estimates an average of two new tissue banks annually, which may be nonmembers of a trade association. Each new tissue bank requires an estimated 64 hours to prepare standard operating procedures (SOPs) under § 1270.31(a) through (d). The requirement for the

development of these written procedures is considered an initial one-time burden. FDA assumes that all current tissue establishments have developed written procedures in compliance with part 1270. Therefore, their information collection burden is for the general review and update of written procedures estimated to take an annual average of 24 hours, and for the recording and justifying of any deviations from the written procedures for § 1270.31(a) and (b), estimated to take an annual average of 1 hour. The information collection burden for maintaining records concurrently with the performance of each significant

screening and testing step and for retaining records for 10 years under § 1270.33(a), (f), and (h), include documenting the results and interpretation of all required infectious disease tests and results and the identify and relevant medical records of the donor required under § 1270.35(a) and (b). Therefore, the burden under these provisions is calculated together in table 1 of this document. The recordkeeping estimates for the number of 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<sup>1</sup>

| 21 CFR Section                                  | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours per Record | Total Hours |
|-------------------------------------------------|----------------------|------------------------------------|----------------------|------------------|-------------|
| 1270.31(a) through (d)                          | 2                    | 1                                  | 2                    | 64               | 128         |
| 1270.31(a) through (d) <sup>2</sup>             | 62                   | 1                                  | 62                   | 24               | 1,488       |
| 1270.31(a) and (b) <sup>3</sup>                 | 62                   | 2                                  | 124                  | 1.0              | 124         |
| 1270.33(a), (f), and (h) and 1270.35(a) and (b) | 62                   | 3,089                              | 191,518              | 1.0              | 191,518     |
| 1270.35(c)                                      | 62                   | 5,719                              | 354,578              | 1.0              | 354,578     |
| 1270.35(d)                                      | 62                   | 715                                | 44,330               | 1.0              | 44,330      |
| Total                                           |                      |                                    |                      |                  | 592,166     |

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

<sup>2</sup> Review and update of SOPs.

<sup>3</sup> Documentation of deviations from SOPs.

Dated: September 24, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0421]

#### Determination That Trilafon Tablets and Three Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined that the four drug products listed in this document were not withdrawn from

sale for reasons of safety or effectiveness. These are drug products with approved new drug applications (NDAs) to which one or more approved abbreviated new drug applications (ANDAs) refer. This determination means that the approval status of the ANDAs is unaffected by the withdrawal from sale of the reference product.

#### FOR FURTHER INFORMATION CONTACT:

Mary Catchings, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are

seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved under an NDA. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA