

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 BURDEN¹

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) ²	62	1	62	24	1,488
1270.31(a) and (b) ³	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

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

² Review and update of SOPs.

³ 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