

- to obtain participation and service use information important to the evaluation's cost-benefit component; and

- to obtain contact information for a future follow-up survey that will be important to achieving high response rates for that survey.

**Respondents:** The respondents to the 30-month follow-up survey are current and former TANF recipients, or individuals in families at risk of needing

TANF benefits (working poor, hard-to-employ) from the two states participating in the evaluation (Illinois and Nebraska). The survey will be administered to both intervention and control groups in each participating site. The estimated sample size for the survey is 984 individuals, including projected samples of 504 in Illinois and 480 in Nebraska. The survey will be conducted primarily by telephone, with

field interviews conducted with those individuals who cannot be interviewed by telephone. OMB already approved the process evaluation component and 18-month follow-up survey for this study.

**Note:** Tennessee has been dropped from the study due to difficulties in recruiting participants to their program. Therefore, the estimated burden is smaller than the one in the first notice.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
30-month follow-up survey .....	246	1	30 minutes or .5 hours	123

Estimated Total Annual Burden Hours: 123

**Additional Information:** Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [rsargis@acf.hhs.gov](mailto:rsargis@acf.hhs.gov).

**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, Attn: Desk Officer for ACF, E-mail address: [lauren\\_wittenberg@omb.eop.gov](mailto:lauren_wittenberg@omb.eop.gov).

Dated: November 10, 2003.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 03-28759 Filed 11-17-03; 8:45 am]

BILLING CODE 4184-01-M

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. 2003P-0300]

#### Determination That Diclofenac Potassium 25-Milligram Tablet Was 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) is announcing its determination that diclofenac potassium 25-milligram (mg) tablet (Cataflam) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for diclofenac potassium 25-mg tablet.

#### **FOR FURTHER INFORMATION CONTACT:**

Carol E. Drew, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 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 a new drug application (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 determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness § 314.62 (21 CFR 314.162)). Regulations also provide that the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On June 27, 2003, The Weinberg Group, Inc., submitted a citizen petition (Docket No. 2003P-0300/CP1) under 21 CFR 10.30 to FDA requesting that the agency determine whether diclofenac potassium 25-mg tablet was withdrawn from sale for reasons of safety or effectiveness. Diclofenac potassium 25-mg tablet is the subject of NDA 20-142, approved in 1993 and held by Novartis Pharmaceuticals Corp. (Novartis). Diclofenac potassium is used for the treatment of osteoarthritis and rheumatoid arthritis. FDA has determined that shortly after the approval of NDA 20-142, Novartis made the decision not to market diclofenac potassium 25-mg tablet in the United States. It was moved from the prescription drug product list to the "Discontinued Drug Product List" section of the Orange Book. FDA has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is