

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, 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.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c)

the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: December 28, 2002.

**Robert Sargis,**

*Report Clearance Officer.*

[FR Doc. 02-32367 Filed 12-23-02; 8:45 am]

**BILLING CODE 4184-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request

*Proposed Projects:*

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Youth .....	1,200	1.5	1	1,800
Caseworker .....	1,800	1.0	1	1,800
Program Admin/staff/extra youth .....	600	1.0	1	600
<i>Estimated Total Annual Burden Hours</i> .....	.....	.....	.....	4,200

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Dated: December 18, 2002.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 02-32368 Filed 12-23-02; 8:45 am]

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*Title:* Evaluation of Independent Living Program Funded Under the Chafee Foster Care Independence Program.

*OMB No.:* New Collection.

*Description:* The Foster Care Independence Act of 1999 (Public Law 106-169) mandates evaluations of promising Independent Living Program administered by state and local child welfare agencies. The Administration for Children and Families proposes an evaluation of six Independent Living Program (ILP) over a five year period using a randomized experimental design. Youth aged 14-21 years receiving ILP services and their caseworkers will be interviewed at three points during the evaluation period. Program administrators, staff, and supplementary youth will also participate in interviews and focus groups conducted at each program site.

*Respondents:* Youth, caseworkers, and program administrators and staff.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Comment Request

*Title:* Online Interstate Referral Guide.

*OMB No.:* 0970-0209.

*Description:* The IRG is an essential reference maintained by OCSE that provides states with an effective and efficient way of viewing and updating state profile, address, and FIPS code information by consolidating data available through numerous discrete sources into a single centralized, automated repository.

*Respondents:* State IV-D Child Support Programs.

#### Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Online IRG .....	54	18	.3	292
<i>Estimated Total Annual Burden Hours</i> .....	.....	.....	.....	292

**Additional Information:** Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 3780 L'Enfant Promenade, SW., Washington, DC 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, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: December 18, 2002.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 78N-0227; DESI 11853]

#### Trimethobenzamide Hydrochloride Injection and Capsules; Drug Efficacy Study Implementation; Final Evaluation

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces the resolution of issues concerning trimethobenzamide hydrochloride injection and capsules. This notice announces the approval of a supplemental new drug application (NDA) for Tigan (trimethobenzamide hydrochloride) Capsules, 300 milligrams (mg), and states that continued marketing of unapproved trimethobenzamide hydrochloride

injection and capsule products is unlawful and is subject to FDA regulatory action.

**ADDRESSES:** Requests for FDA's opinion on whether a supplement to an abbreviated new drug application (ANDA) is required for a specific trimethobenzamide hydrochloride injection product should be identified with Docket No. 78N-0227 and reference number DESI 11853 and be directed to the Office of Generic Drugs (HFD-600), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., rm. 150, Rockville, MD 20855-2773. Requests for an opinion on the applicability of this notice to a specific trimethobenzamide hydrochloride injection or capsule product should be identified with Docket No. 78N-0227 and reference number DESI 11853 and directed to the Division of Prescription Drug Compliance and Surveillance (HFD-330), Center for Drug Evaluation and Research, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

**FOR FURTHER INFORMATION CONTACT:** Brian L. Pendleton, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

As part of its Drug Efficacy Study Implementation (DESI) program, in a notice published in the **Federal Register** of February 24, 1971 (36 FR 3435) (the 1971 notice), FDA announced its conclusion that certain drug products containing trimethobenzamide hydrochloride were: (1) Probably effective for nausea and vomiting due to radiation therapy or travel sickness and for emesis associated with operative procedures, labyrinthitis, or Meniere's syndrome; (2) lacking substantial evidence of effectiveness for the treatment of nausea and vomiting due to infections, underlying disease processes, or drug administration; and (3) possibly effective for all other labeled indications. The 1971 notice listed three trimethobenzamide

hydrochloride products: Tigan Solution for Injection (NDA 11-853), Tigan Capsules (NDA 11-854), and Tigan Suppositories (NDA 11-855). Roche Laboratories held the NDAs for these three products.

In the **Federal Register** of January 9, 1979 (44 FR 1017) (the 1979 notice), FDA published a notice announcing that the agency was reclassifying trimethobenzamide hydrochloride injection and capsules to effective for certain indications and to lacking substantial evidence of effectiveness for their other (previously designated) less-than-effective indications. Specifically, FDA concluded that trimethobenzamide hydrochloride injection and capsules are effective for the treatment of postoperative nausea and vomiting and for nausea associated with gastroenteritis. The agency also concluded that trimethobenzamide hydrochloride injection and capsules lack substantial evidence of effectiveness for their other labeled indications. (In the same issue of the **Federal Register** (44 FR 2021), FDA published a notice reclassifying trimethobenzamide hydrochloride suppositories to lacking substantial evidence of effectiveness and proposed to withdraw approval of NDAs for trimethobenzamide hydrochloride suppositories.)

The 1979 notice stated that two NDAs for trimethobenzamide hydrochloride injection and capsules not included in the February 1971 notice were affected by the new notice: NDA 17-530, for Tigan Injection, and NDA 17-531, for Tigan Capsules, both held by Beecham Laboratories (Beecham) (44 FR 2017 at 2018). The 1979 notice stated that, according to bioavailability studies submitted by Beecham, the relative bioavailability or extent of absorption of a 250-mg capsule was 56-62 percent of that of the 200-mg intramuscular injection. Based on these studies, FDA concluded that the oral dose of trimethobenzamide hydrochloride should be approximately two times the intramuscular dose. FDA noted that on May 2, 1978, Beecham supplemented its NDA for Tigan Capsules to reformulate the capsule dosage form from 100 mg