

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

21 CFR section	Number of record-keepers	Number of records per record-keeper	Total annual records	Average burden per record-keeping	Total hours
1140.32 (Format and content requirements for labeling and advertising) .....	1	1	1	1	1
Total .....	.....	.....	.....	.....	1

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1140.32 .....	1	1	1	1	1

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

The burden hour estimates for this collection of information were based on industry-prepared data and information regarding pharmaceutical advertising and cigarette and smokeless tobacco product advertising expenditures. The burden collection does not include reporting burdens associated with providing established names on labels and statements of intended use because section 102 of the Tobacco Control Act required that these provisions be struck from the reissued final rule (previously included in 897.24 and 897.32(c)).

Section 1140.30 (previously 897.30) requires manufacturers, distributors, and retailers to observe certain format and content requirements for labeling and advertising, and requires manufacturers, distributors, and retailers to notify FDA if they intend to use an advertising medium that is not listed in the regulations. The concept of permitted advertising in 1140.30 is sufficiently broad to encompass most forms of advertising. FDA estimates that approximately 300 respondents will submit an annual notice of alternative advertising, and the Agency has estimated it should take 1 hour to provide such notice.

For the recordkeeping and disclosure requirements, 1140.32 (previously 897.32) requires competent and reliable survey evidence to establish whether a newspaper, magazine, periodical, or other publication qualifies as an “adult” publication. Section 1140.32 also requires the use of a black text on a white background for labeling and advertising. The respondent and hourly burden for recordkeeping and disclosure under this section (2 burden hours total) reflect placeholders for the number of manufacturers who would keep records under this section.

During the next 3 years, FDA does not intend to enforce the recordkeeping and disclosure requirements of 1140.32 and has revised the burden to act as a placeholder in the event FDA exercises its authority to enforce the requirements of this section in the future.

FDA estimates that the total time required for this collection of information is 302 hours.

Dated: September 21, 2012.

**Leslie Kux,**  
*Assistant Commissioner for Policy.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2012–N–0001]

**Gastrointestinal Drugs Advisory Committee; Notice of Postponement of Meeting**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is postponing the Gastrointestinal Drugs Advisory Committee Meeting scheduled for October 15, 2012. This meeting was announced in the **Federal Register** of August 16, 2012 (77 FR 49446). The postponement is due to scheduling issues.

**FOR FURTHER INFORMATION CONTACT:** Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax:

301–847–8533, email: [GIDAC@fda.hhs.gov](mailto:GIDAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), or visit our Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: September 25, 2012.

**Jill Hartzler Warner,**  
*Acting Associate Commissioner for Special Medical Programs.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; Comment Request; CareerTrac**

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Fogarty International Center (FIC), National Institute of General Medical Science (NIGMS), National Cancer Institute (NCI), and National Library of Medicine (NLM) of the National Institutes of Health (NIH), in conjunction with the National Institute of Environmental Health Sciences (NIEHS), including the Intramural Research and Training Award (IRTA) and Superfund Research Program (SRP) within NIEHS, has submitted to the Office of Management and Budget (OMB) for review and approval. This proposed information collection was previously published in the **Federal Register**, Vol. 77, No. 106, on June 1, 2012, pages 32648–32649 and allowed 60 days for public comment. One public comment was received from the Association for Research in Vision and Ophthalmology (ARVO). The