ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Estimated Total Annual Burden Hours: 13,746				

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 Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 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 clarify 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: July 8, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–18658 Filed 7–13–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Relocation of the Dockets Management Branch; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 16, 1998 (63 FR 32888). The document announced the relocation and partial closing of the Dockets Management Branch (DMB). The document published with an incorrect zip code. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Jennie C. Butler, Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20852, 301–827–6860.

In FR Doc. 98–15878, appearing on page 32888, in the **Federal Register** of Tuesday, June 16, 1998, the following corrections are made:

1. On page 32888, in the second column, under ''**SUPPLEMENTARY INFORMATION**,'' in line six, the zip code is corrected to read ''20852,'' and in the second paragraph, in line eleven, the zip code is corrected to read ''20852.''

Dated: July 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–18691 Filed 7–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0481]

Guidance for Industry on 180–Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''180–Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act.'' The purpose of the guidance is to inform the public of FDA's application of the 180-day generic drug exclusivity provisions of the Federal Food, Drug, and Cosmetic Act (the act) in light of recent court decisions on the issue.

DATES: Written comments may be submitted on the guidance document by October 13, 1998. General comments on the agency guidances are welcome at any time.

ADDRESSES: Copies of the guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm.'' Submit written requests for single copies to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the guidance to the Dockets Management Branch, (HFD–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jerry Phillips, Center for Drug Evaluation and Research (HFD–610), 7500 Standish Pl., Rockville, MD 20855, 301–827–5846.

SUPPLEMENTARY INFORMATION: A requirement of FDA's regulations implementing the 180-day generic drug exclusivity provisions of the act has recently been successfully challenged in court. Section 314.107(c)(1) (21 CFR 314.107(c)(1)) applies and interprets section 505(j)(5)(B)(iv) of the act (21 U.S.C. 355(j)(5)(B)(iv)). Section 314.107(c)(1) contains the ''successful defense'' provision, which requires an abbreviated new drug application (ANDA) applicant to be sued for patent infringement and to prevail in the litigation in order to receive the 180-day period of marketing exclusivity. Two recent circuit court decisions, *Mova Pharmaceutical Corp.* v. *Shalala*, No. 97–5082, 1998 U.S. App. Lexis 7391 (D.C. Cir. Apr. 14, 1998) and *Granutec, Inc.* v. *Shalala*, No. 97–1873 and No. 97–1874, 1998 U.S. App. LEXIS 6685, (4th Cir. Apr. 3, 1998), held that the ''successful defense'' requirement was not supported by the act. The effect of these decisions, together with a June 1, 1998, order of the district court in *Mova*, is that FDA will not enforce the ''successful defense'' provisions of § 314.107(c)(1).

FDA intends to formally remove the ''successful defense'' provisions from § 314.107(c)(1), but that process is not complete. Following withdrawal of the regulatory provision, FDA expects to begin a rulemaking to issue new

regulations under section 505(j)(5)(B)(iv) of the act. In the meantime, the agency must make exclusivity decisions for ANDA's that are nearing approval. Until such time as the rulemaking process is complete, FDA will regulate directly from the statute and will make decisions on 180-day generic drug exclusivity on a case-by-case basis.

The guidance is intended to provide industry with information on how FDA is applying section 505(j)(5)(B)(iv) of the act in light of the decisions in *Mova* and *Granutec*. The agency will revise this guidance as additional interpretations are made.

The guidance is being implemented immediately without prior public comment because the guidance is needed to explain FDA's application of the statute in light of recent court decisions. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

This guidance is a level 1 guidance consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on 180-day generic drug exclusivity under the Hatch-Waxman Amendments. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the act.

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 7, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–18690 Filed 7–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited 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) ways to enhance 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.

Proposed Project

Grantee Reporting Requirements for the Rural Health Network Development Grant Program (OMB NO. 0915–0218)—Extension.

This is a request for extension of the reporting requirements for the Rural Network Development Grant Program authorized by section 330A of the Public Health Service Act as amended by the Health Centers Consolidation Act of 1996 (Public Law 104–229). The purpose of the program is to assist in the development of vertically integrated networks of health care providers in rural communities. Grantees will be working to change the delivery system in their service areas and will be using the Federal funds to develop network capabilities.

Grantees submit semiannual reports which provide information on progress towards goals and objectives of the network, progress toward developing the governance and organizational arrangements for the network, specific network activities, certain financial data related to the grant budget, and health care services provided by the network.

The information is used to evaluate progress on the grants, to understand barriers to network development in rural areas, to identify grantees in need of technical assistance, and to identify best practices in the development of provider networks in rural communities.

The information is also used to begin to evaluate the impact of networks on access to care.

To minimize the burden on grantees, the reports will are submitted electronically. The estimated burden is as follows:

Type of respondent	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Grantees	40	2	20	1,600

Send comments to: HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: July 7, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–18692 Filed 7–13–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: June 1998

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of June 1998, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party.