

"Measuring Improved Metrics of EMF Exposure in an Electric Utility". The study's goal is to test the feasibility of combining measurements of these new EMF exposure metrics with existing epidemiologic data to produce a more valid assessment of EMF health risks. Designated reviewers will individually critique the study protocol and provide comments on the conduct of the study and its prospects for achieving its goals. Others will be given an opportunity to provide individual comments.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information and a Copy of the Protocol:* Joseph Bowman, Non-ionizing Radiation Section, Engineering and Physical Hazards Branch, Division of Applied Research and Technology, NIOSH, CDC, 4676 Columbia Parkway, M/S C-27, Cincinnati, Ohio 45226, telephone 513/533-8143.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: March 30, 2001.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 01-8386 Filed 4-4-01; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Grant to Welfare Information Network

**AGENCY:** Office of Family Assistance, ACF, DHHS.

**ACTION:** Grant award announcement.

**SUMMARY:** Notice is hereby given that an award is being made to the Welfare Information Network of Washington, DC in the amount of \$75,000 for information dissemination activities on welfare reform. After the appropriate reviews, it has been determined that this proposal qualifies as a sole source award. Over the past five years, the Welfare Information Network (WIN) has been one of the leading nonprofit organizations in disseminating information and materials on welfare reform. The WIN network is a very unique organization in the welfare reform community. It has created a database on the cutting edge of Welfare to Work promising strategies through a synthesis of the latest research, site visits, and surveys of practitioners and service providers. The WIN organization has been an extremely valuable partner

with the Office of Family Assistance in several clearinghouse and networking activities. This partnership with the WIN Organization has proven to be invaluable to States and communities in obtaining the information, policy analysis, and technical assistance they need to develop and implement changes that have helped to reduce dependency and promote the well-being of children and families. The period of this funding will extend through May 31, 2002.

**FOR FURTHER INFORMATION CONTACT:** Paul Maiers, Office of Family Assistance, Administration for Children and Families, 370 L'Enfant Promenade, SW, Washington, DC 20447, Telephone: 202-401-5438.

Dated: March 30, 2001.

**Samara Weinstein,**

*Deputy Director, Office of Family Assistance.*

[FR Doc. 01-8423 Filed 4-4-01; 8:45 am]

**BILLING CODE 4184-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 97N-0472]

#### Agency Information Collection Activities; Announcement of OMB Approval; Petition for Administrative Stay of Action

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Petition for Administrative Stay of Action" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn P. Capezuto, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 5, 2001 (66 FR 1144), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0194. The approval expires on March 31, 2004. A

copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: March 29, 2001.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

[FR Doc. 01-8306 Filed 4-4-01; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1666]

#### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

**DATES:** Submit written comments on the collection of information by May 7, 2001.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions (OMB Control No. 0910-0305—Extension

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) requires patent owners to submit to FDA information about patents that cover approved drugs. Generic copies of

these drugs may be approved when the patents expire is a generic company certifies that the patent is invalid or will not be infringed. In such cases, the generic company must notify the patent owner about the certification, and approval of the drug may not be made effective until after the court decides the patent infringement suit or a period of 36 months, whichever occurs first. In addition, section 505 of the act provides several periods of marketing exclusivity ranging from 3 to 10 years (depending primarily on the nature of the innovation). If a drug product receives marketing exclusivity, FDA will not approve (or, in limited cases not receive) an abbreviated new drug application (ANDA) for the drug product.

Under the authority found in sections 505 and 701 of the act (21 U.S.C. 371), FDA issued regulations governing patent and exclusivity provisions in part 314 (21 CFR part 314). The regulations provide instructions for new drug applications (NDA) applications (including section 505(b)(2) of the act applicants) and ANDA applicants on how to file patent information and request marketing exclusivity; require patent certification information for section 505(b)(2) applications and ANDA's; require information for requests for marketing exclusivity for NDA's (including section 505(b)(2) applications and certain NDA

supplements); and require patent information for NDA's.

The specific reporting requirements that are the subject of this information collection are as follows:

- § 314.50(i)—Requires the submission of patent certification information
- § 314.50(j)—Requires the submission of marketing exclusivity information
- § 314.5—Requires notice of certification of invalidity or noninfringement of a patent
- § 314.53—Requires the submission of patent information.
- § 314.54(a)—Requires the submission of marketing exclusivity information.
- § 314.70(e)—Requires the submission of patent information
- § 314.70(f)—Requires the submission of marketing exclusivity information
- § 314.94(a)(12)—Requires the submission of patent certification information
- § 314.95—Requires notice of certification of invalidity or noninfringement of a patent.
- § 314.107(c)(4), (e)(2)(iv), and (f)—Requires notice of the date of commercial marketing; a copy of the entry (c)(4), (e)(2)(iv), of the order or judgment; notice of the filing of legal action after notice of certification.

Applicants must provide information on patents to FDA to enable the agency to determine whether a product is covered by a patent or whether approval of a proposed drug product would result

in patent infringement. The agency lists the patent information as a reference of potential applicants. If an applicant believes a patent is invalid or would not be infringed, Federal law also requires it to notify the patent holder. FDA approval, in such cases, is affected should there be any patent litigation. Failure to provide this information would result in an incomplete application and constitute grounds for refusing to approve the application.

Applicants submitting NDA's are required under the act to provide information on certain patents that cover their drug products. The agency lists this patent information in its publication entitled List of Approved Drug Products With Therapeutic Equivalence Evaluations, which is available on the Internet at [www.fda.gov/Cder/OB](http://www.fda.gov/Cder/OB).

To promote product innovation, the act also gives NDA applicants several periods of "market exclusivity" ranging from 3 to 10 years (depending primarily on the nature of the innovation). If a drug product receives marketing exclusivity, FDA will not approve (or, in limited cases, even receive) an ANDA for the drug product during that time period.

In the **Federal Register** of January 3, 2001 (66 FR 372), the agency requested comments on the proposed collections of information. No significant comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

21 CFR Section	No. of respondent per response	Annual frequency per response	Total annual responses	Hours per response	Total hours
Patent Information. 314.50(h). 314.53. 314.70(e) .....	85	3.8	325	2	650
Patent Certification Information. 314.50(i). 314.94(a)(12) .....	97	3.4	331	2	662
Notice of Certification of Invalidity or Noninfringement of a Patent. 314.52. 314.95 .....	37	2	75	16	1,200
Marketing Exclusivity Information 314.50(j). 314.54(a)(1)(vii). 314.70(f) .....	92	2.7	250	2	500
Notification of Date of Commercial Marketing; Entry of the Order or Judgement; Filing of Legal Action. 314.107(c)(4), (e)(2)(iv), (f)(2), and (f)(3) .....	34	2	71	1	71

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

Dated: March 29, 2001.  
**William K. Hubbard,**  
*Senior Associate Commissioner for Policy, Planning, and Legislation.*  
 [FR Doc. 01-8307 Filed 4-4-01; 8:45 am]  
 BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Health Care Financing Administration**  
**[Document Identifier: HCFA-10021]**  
**Notice; Correction**  
**ACTION:** Notice; correction.

**SUMMARY:** In the **Federal Register** issue of Monday, March 26, 2001, make the following correction:  
*Correction:* In the **Federal Register** issue of Monday, March 26, 2001, Volume 66: FR Doc. 01-7327, on page 16480, "Responses: 12,600" in the 16th line of the first full paragraph in column 2 should read "Responses: 12,600,000."  
 Dated: March 28, 2001.  
**Julie Boughn,**  
*Manager, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.*  
 [FR Doc. 01-8404 Filed 4-4-01; 8:45 am]  
 BILLING CODE 4120-03-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Care Financing Administration**  
**[Document Identifier: HCFA-R-297]**

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Health Care Financing Administration, DHHS. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Existing collection in use without an OMB control number.  
*Title of Information Collection:* Request for Employment Information.  
*Form No.:* HCFA-R-297 (OMB# 0938-0787).

*Use:* This form is needed to determine whether a beneficiary can enroll in Part B Medicare and/or qualify for premium

reduction. This form is used by the Social Security Administration to obtain information from employers regarding whether a Medicare beneficiary's coverage under a group health plan is based on current employment.

*Frequency:* On occasion.  
*Affected Public:* Business or other for-profit.  
*Number of Respondents:* 5,000.  
*Total Annual Responses:* 5,000.  
*Total Annual Hours:* 750.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at <http://www.hcfa.gov/regs/prdact95.htm>, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards Attention: Melissa Musotto Room N2-14-26 7500 Security Boulevard Baltimore, Maryland 21244-1850.

**Julie Boughn,**  
*Manager, HCFA Office of Information Service, Security and Standards Group, Division of HCFA Enterprise Standards.*  
 [FR Doc. 01-8405 Filed 4-4-01; 8:45 am]  
 BILLING CODE 4120-03-P