Performance Report is required by federal statute. Each State Developmental Disabilities Council must submit an annual report for the preceding fiscal year of activities and accomplishments. Information provided in the Program Performance Report will be used (1) in the preparation of the biennial Report to the President, the Congress, and the National Council on Disabilities and (2) to provide a national perspective on program accomplishments and continuing challenges. This information will also be used to comply with requirements in the Government Performance and Results Act of 1993.

*Respondents:* State Councils.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| State Council on Developmental Disabilities Program Performance Report .. | 56 | 1 | 138 | 7,590 |

*Estimated Total Annual Burden Hours:* 7,590.

**Additional Information**

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 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. Email address: *infocollection@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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.*

Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2012–10426 Filed 4–30–12; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Comment Request

*Title:* Measure Development: Quality of Family-Provider Relationships in Early Care and Education.

*OMB No.:* New collection.

**Description**

The Office of Planning, Research and Evaluation (OPRE), the Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing a data collection activity as part of the development of an early care and education (ECE) quality measurement tool to assess family-provider relationships that support positive child developmental outcomes and family wellbeing. The major goal of this project is to develop a measure of the quality of family-provider relationships that will be (1) applicable across multiple types of early care and education settings and diverse program structures (including Head Start/Early Head Start); (2) sensitive across cultures associated with racial, ethnic, and socioeconomic characteristics; and (3) reliable in both English and Spanish. At this time, four self-administered surveys (one for center- and home-based care directors, one for child care providers/teachers, and two for parents) and an environmental checklist have been developed, based on a literature review, a review of existing measures, and information collected through focus groups (under OMB Clearance 0970–0356) and cognitive interviews (under OMB Clearance 0970–0355).

To test these measures, two stages of data collection activities are proposed for this information collection request: A pilot test and a field test.

The pilot test data will be used to examine the distribution of the items and to determine whether they behave in a manner consistent with the conceptual model that was developed as part of the project. The pilot test will also test data collection procedures prior to conducting a large-scale field test. Any problematic items or procedures identified by the pilot test will be corrected and revisions submitted to OMB before the field test.

The purpose of the field test is to obtain sufficient data on a diverse population to enable full psychometric testing of the measures and compare subgroups to ensure that the measure can be used in diverse ECE settings.

*Respondents:* In both the pilot and the field tests, the respondents will include directors of center—based child care programs, home-based child care programs, Early Head Start programs, and Head Start programs; center-based and home-based child care providers and ECE teachers; and parents whose children are enrolled in these diverse types of ECE settings.

ANNUAL BURDEN ESTIMATE—PILOT AND FIELD TESTS

| Instrument | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Total annual burden hours |
|---|---|---|---|---|
| Screening questions | 945 | 1 | 0.05 | 47 |
| Director Survey | 143 | 1 | 0.08 | 11 |
| Provider/Teacher Survey | 253 | 1 | 0.17 | 43 |
| Parent Survey about FSWs | 76 | 1 | 0.17 | 13 |
| Parent Survey about Teachers | 475 | 1 | 0.17 | 81 |
| Environmental Checklist | 945 | 1 | 0.17 | 161 |

*Estimated Total Annual Burden Hours:* 356.

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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* 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: April 23, 2012.

**Steven Hanmer,**

*Reports Clearance Officer.*

[FR Doc. 2012–10305 Filed 4–30–12; 8:45 am]

**BILLING CODE 4184–22–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–P–0025]**

## Determination That GRIFULVIN V (Griseofulvin Microcrystalline) Tablets, 250 Milligrams, 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) has determined that GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 milligrams (mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for griseofulvin microcrystalline tablets, 250 mg, if all other legal and regulatory requirements are met.

**FOR FURTHER INFORMATION CONTACT:** Nancy Hayes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6244, Silver Spring, MD 20993–0002, 301–796–3601.

**SUPPLEMENTARY INFORMATION:** In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants 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. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed 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 (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, is the subject of ANDA 062279, held by OrthoNeutrogena, and approved on June 2, 1980. GRIFULVIN V is indicated for the treatment of certain ringworm infections (tinea corporis, tinea pedis, tinea cruris, tinea barbae, tinea capitis, and tinea unguium) when caused by a certain genera of fungi.

GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Arthur Y. Tsien of Olsson Frank Weeda Terman Bode Matz PC submitted a citizen petition on behalf of a client, dated January 7, 2011 (Docket No. FDA–2011–P–0025), under 21 CFR 10.30, requesting that the Agency determine whether GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, from sale. We have also independently reviewed relevant literature and data for possible postmarketing adverse event reports. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to GRIFULVIN V (griseofulvin microcrystalline) tablets, 250 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.