prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and CMS 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 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 30, 2002.

John P. Burke III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, CMS Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards.

[FR Doc. 02–14277 Filed 6–6–02; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Planning, Research and Evaluation; Grant to Metropolitan Family Services

AGENCY: Office of Planning, Research and Evaluation, Administration for Children and Families (ACF), Department of Health and Human Services (DHHS)

ACTION: Award announcement.

SUMMARY: Notice is hereby given that a noncompetitive grant award is being made to Metropolitan Family Services to strengthen the relationship between fathers and their children, increase their access to the labor force, improve their financial literacy, and strengthen their support systems.

As a Congressional set-aside, this 17-month project is being funded noncompetitively. Metropolitan Family Services is uniquely qualified to implement this project because of its decades long experience in providing services for strengthening families and communities. The cost of this 17-month project is $400,000.

FOR FURTHER INFORMATION CONTACT: K.A. Jagannathan, Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, telephone: 202–205–4829.

Dated: May 28, 2002.

Howard Rolston,

Director, Office of Planning, Research and Evaluation.

[FR Doc. 02–14320 Filed 6–6–02; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0587]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling Forms FDA 356h and 2567; and Revocation and Suspension

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.

DATES: Submit written comments on the collection of information by July 8, 2002.

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: Stuart Shapiro, Desk Officer for FDA.

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

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.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling Forms FDA 356h and 2567; and Revocation and Suspension (OMB Control Number 0910–0338)—Extension

Under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601). Section 601.2(a) requires a manufacturer of a biological product to submit an application with accompanying information, including labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under 21 CFR 610.60, 610.61, and 610.62. Section 601.12(a) provides the general requirements for submitting a change to an approved application. Section 601.12(b), (c), and (d) requires applicants to follow specific procedures in informing FDA of each change, established in an approved license application, in the product, production process, quality controls, equipment, facilities, or responsible personnel. The appropriate procedure depends on the potential for the change to have a substantial, moderate, minimal, or no adverse effect on the safety or effectiveness of the product. Section 601.12(e) requires applicants to submit a protocol, or change to a protocol, as a supplement requiring FDA approval before distributing the product. Section 601.12(f)(1), (f)(2), and (f)(3) requires applicants to follow specific procedures in reporting labeling changes to FDA. Section 601.12(f)(4) requires applicants to report to FDA advertising and promotional labeling and any changes. Section 601.45 requires applicants to submit to the agency for consideration, during the preapproval review period, copies of all promotional materials, including promotional labeling as well as advertisements. Section 601.27(a) requires that applications for new biological products contain data that are adequate to assess the safety and effectiveness of the biological product for the claimed indications in pediatric subpopulations, and to support dosing and administration information. Section 601.27(b) provides that an applicant may request a deferred submission of some or all assessments of safety and effectiveness required under § 601.27(a). Section 601.27(c) provides that an applicant may request a full or partial waiver of the requirements under § 601.27(a). Section 601.28 requires sponsors of licensed biological products to submit the information in section

601.28(a), (b), and (c) to the Center for Biologics Evaluation and Research (CBER) each year, within 60 days of the anniversary date of approval of the license. Section 601.28(a) requires sponsors to submit to FDA a brief summary stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Section 601.28(b) requires sponsors to submit to FDA an analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. Section 601.28(c) requires sponsors to submit to FDA a statement on the current status of any postmarketing studies in the pediatric population performed by, on or behalf of, the applicant. Sections 601.33 through 601.35 clarify the information to be submitted in an application to FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals. In addition to §§ 601.2 and 601.12, there are other regulations in parts 640, 660, and 680 (21 CFR parts 640, 660, and 680) that relate to information to be submitted in a license application or supplement for certain blood or allergenic products: §§ 606.110(b), 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), 660.51(a)(4), and 680.1(b)(2)(iii). In table 1 of this document, the burden associated with the information collection requirements in these regulations is included in the burden estimate for §§ 601.2 and 601.12. A regulation may be listed under more than one paragraph of § 601.12 due to the type of category under which a change to an approved application may be submitted. In addition, the burden associated with the information collection requirements in § 601.27(a) and §§ 601.33 through 601.35 is included in the burden estimate for § 601.2 since these regulations deal with information to be provided in an application. Sections 600.15(b) (21 CFR 600.15(b)) and § 610.53(d) (21 CFR 610.53(d)) require the submission of a request for an exemption or modification regarding the temperature requirements during shipment and from dating periods, respectively, for certain biological products. Section 601.25(b) requests interested persons to submit, for review and evaluation by an advisory review panel, published and unpublished data and information pertinent to a designated category of biological products that have been licensed prior to July 1, 1972. Section 601.26(f) requests that licensees submit to FDA a written statement intended to show that studies adequate and appropriate to resolve questions raised about a biological product have been undertaken for a product if designated as requiring further study under the reclassification procedures. Section 601.5(a) requires a licensee to submit to FDA notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires the licensee to notify selling agents and distributors upon suspension of its license, and provide FDA with records of such notification. Section 680.1(c) requires manufacturers to update annually the list of source materials and the suppliers of the materials. In July 1997, FDA revised Form FDA 356h ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use''' to harmonize application procedures between CBER and the Center for Drug Evaluation and Research (CDER). The application form serves primarily as a checklist for firms to gather and submit to the agency studies and data that have been completed. The checklist helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. The form provides key information to the agency for efficient handling and distribution to the appropriate staff for review. The estimated burden hours for submissions using FDA Form 356h to CDER are reported under OMB control number 0910–0001. Form FDA 2567 ''Transmittal of Labels'' and circulars (is used by manufacturers of licensed biological products to submit labeling (e.g., circulars, package labels, container labels, etc.) and labeling changes for FDA review and approval. The labeling information is submitted with the form for license applications, supplements, or as part of an annual report. Form FDA 2567 is also used for the transmission of advertisements and promotional labeling. Form FDA 2567 serves as an easy guide to assure that the manufacturer has provided the information required for expeditious handling of their labeling by CBER. For advertisements and promotional labeling, manufacturers of licensed biological products may submit to CBER either Form FDA 2567 or Form FDA 2253. Form FDA 2253 was previously used only by drug manufacturers regulated by CDER. In August of 1998, FDA revised and harmonized Form FDA 2253 so the form may be used to transmit specimens of promotional labeling and advertisements for biological products as well as for prescription drugs and antibiotics. The revised and harmonized form updates the information about the types of promotional materials and the codes that are used to clarify the type of advertisement or labeling submitted; clarifies the intended audience for the advertisements or promotional labeling (e.g., consumers, professionals, news services); and helps ensure that the submission is complete. Under table 1 of this document, the number of respondents is based on the estimated annual number of manufacturers that submitted the required information to FDA in fiscal year (FY) 2000, or the number of submissions received in FY 2000. Based on information obtained from CBER's database system, there are an estimated 350 licensed biologics manufacturers. However, not all manufacturers will have any submissions in a given year and some may have multiple submissions. The total annual responses are based on the estimated number of submissions (e.g., license applications, labeling and other supplements, protocols, advertising and promotional labeling, notifications) received annually by FDA. Based on previous estimates, the rate of submissions is not expected to change significantly in the next few years. The hours per response are based on information provided by industry and past FDA experience with the various submissions or notifications. The hours per response include the time estimated to prepare the various submissions or notifications to FDA, and, as applicable, the time required to fill out the appropriate form and collate the documentation. Additional information regarding these estimates is provided below as necessary. Under §§ 601.12(f)(4) and 601.45, manufacturers of biological products may use either Form FDA 2567 or Form FDA 2253 to submit advertising and promotional labeling. In FY 2000, CBER received 4,302 submissions of advertising and promotional labeling from 117 manufacturers. FDA estimates that approximately 36 percent of those submissions were received with Form FDA 2567 resulting in an estimated 1,549 submissions by 42 manufacturers. The burden hours for the remaining submissions received using Form FDA 2253 are reported under OMB control number 0910–0376. Under §§ 600.15(b) and 610.53(d), FDA receives very few requests for an exemption or modification to the requirements, therefore, FDA has estimated one respondent per year in table 1 of this document to account for the rare

instance in which a request may be made. Under § 601.25(b)(3), FDA estimates no burden for this regulation since all requested data and information had been submitted by 1974. Under § 601.26(f), FDA estimates no burden for this regulation since there are no products designated to require further study and none are predicted in the future. However, based on the possible reclassification of a product, the labeling for the product may need to be revised, or a manufacturer, on its own initiative, may deem it necessary for further study. As a result, any changes to product labeling would be reported under § 601.12. Under § 601.6(a), the total annual responses is based on FDA estimates that establishments may notify an average of 20 selling agents and distributors of such suspension and provide FDA with the records of such notification. The number of respondents is based on the estimated annual number of suspensions by FDA of a biologics license. There were also 1,585 amendments to an unapproved application or supplement and 21 resubmissions (total of 1,606 submissions) submitted in FY 2000 using Form FDA 356h.

One letter of comment was received in response to the 60-day notice on the information collection in which we received one comment on the proposed information collection.

The comment stated that we should revise various regulations to harmonize regulations between CBER and CDER. The comment cited many specific provisions, with none of the cited provisions being affected by the proposed information collection, and recommended specific changes to those provisions. For example, the comment asked that we delete § 610.12 (21 CFR 610.12) regarding sterility for bulk materials, that we revise 21 CFR 610.11, § 610.12, and 21 CFR 610.13 and 610.30 to delete references to specific tests, and that we redefine ''manufacturer'' in 21 CFR 600.3(t). The comment also asked us to address ''outdated'' safety reporting regulations; to permit multiple product facilities (citing 21 CFR 600.11(e)(3)); and to expedite followup actions after inspections.

The comment's suggested regulatory revisions pertain to provisions or matters that are outside the scope of the proposed information collection. Consequently, we decline to adopt the comment's recommendations.

The comment relevant to the information collection in the 60-day notice stated that Form FDA 2567 is only used to submit labels to CBER and that CDER does not use this form. The comment stated that the requirement to use only one form for one Center imposes an additional burden (but did not describe the additional burden), and suggested that CBER and CDER use the same form or not use the form at all.

We are considering whether to retain Form FDA 2567 for labeling purposes, but because the issue of eliminating the form is complex, we won't have a decision on the matter before the OMB approval expires. Therefore, we are renewing the form until a final decision is reached on the use of the form. Manufacturers already have the option of submitting to CBER and CDER Form FDA 2253 for the submission of advertising and promotional labeling. However, any additional burden of submitting the form with a biologics license application is minimal because the time required to complete this form is estimated to average 10 minutes.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Part[2]	Form FDA No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
601.2(a), 610.60, 610.61, and 610.62	2567 and 356h	22	3.64	80	1,600	128,000
601.12(b)(1) and (b)(3)	356h	168	4.98	837	80	66,960
601.12(c)(1) and (c)(3)	356h	119	6.63	789	50	39,450
601.12(c)(5)	356h	58	3.52	204	50	10,200
601.12(d)	356h	83	1.72	143	10	1,430
601.12(e)	356h	70	1	70	20	1,400
601.12(f)(1)	2567	37	2.08	77	40	3,080
601.12(f)(2)	2567	45	1	45	20	900
601.12(f)(3)	2567	20	1	20	10	200
601.12(f)(4) and 601.45	2567	42	36.88	1,549	10	15,490
600.15(b)	356h	1	1	1	8	8
610.53(d)	356h	1	1	1	8	8
601.25(b)(3)	NA	0	0	0	0	0
601.26(f)	NA	0	0	0	0	0
601.27(b)	NA	5	1	5	24	120
601.27(c)	NA	3	1.33	4	8	32
601.28(a)	NA	69	1	69	8	552
601.28(b)	NA	69	1	69	24	1,656
601.28(c)	NA	69	1	69	1.5	103.5
601.5(a)	NA	25	1	25	.33	8.25
601.6(a)	NA	2	21	42	.33	14
680.1(c)	NA	10	1	10	2	20
Amendments and Resubmissions	356h	350	4.59	1,606	20	32,120
Total						301,751.75

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] The reporting requirement under §§ 601.27(a), 601.33, 601.34, 601.35, and 680.1(b)(2)(iii) is included in the estimate under § 601.2(a). The reporting requirement under §§ 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), and 640.72(a) and (b)(2) is included in the estimate under § 601.12(b). The reporting requirement under §§ 640.25(c) and 640.56(c) is also included in the estimate under § 601.12(c)(3).

Dated: May 31, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–14390 Filed 6–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 84N–0102]

Cumulative List of Orphan Drug and Biological Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the cumulative list of orphan drug and biological designations as of December 31, 2001. FDA has announced the availability of previous lists, which are updated monthly, identifying the drugs and biologicals granted orphan designation under the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the cumulative list of orphan drug and biological designations are available from the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

FOR FURTHER INFORMATION CONTACT: Jeffrey Fritsch, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan designation of their drug or biological under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act, which requires public notification of designations, FDA maintains a cumulative list of orphan drug and biological designations. This list includes the name of the drug or biological, the specific disease/condition for which the drug or biological is designated, and information about the sponsor such as the name, address, telephone, and contact.

At the end of each calendar year, the agency publishes a cumulative list of orphan drug and biological designations current through the calendar year. The list that is the subject of this notice is the cumulative list of orphan drug and biological designations through December 31, 2001, and, therefore, brings the April 3, 2001 (66 FR 17718) publication up to date. This list is available upon request from the Dockets Management Branch (see **ADDRESSES**). Those requesting a copy should specify Docket No. 84N–0102, which is the docket number for this notice. In addition, the list is updated monthly and is available upon request from OPD or FDA's Dockets Management Branch (see **ADDRESSES**). The current list is also available at http://www.fda.gov/orphan.

The orphan designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing a drug or biological for an orphan indication must apply for orphan designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which designation is requested (21 CFR 316.23). Copies of the orphan drug regulations (21 CFR part 316) (57 FR 62076, December 29, 1992) and explanatory background materials for use in preparing an application for orphan designation may be obtained from OPD (see **ADDRESSES**).

The names of the drugs and biologicals shown in the cumulative list of orphan designations may change upon marketing approval/licensing, reflecting the established, proper name approved by FDA. Because drugs and biologicals not approved/licensed for marketing are investigational, the appropriate established, proper name has not necessarily been assigned.

Dated: May 30, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–14327 Filed 6–6–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0242]

Pharmacy Compounding Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for FDA staff and industry entitled ''Sec. 460.200 Pharmacy Compounding.'' The document being issued with this notice provides guidance to drug compounders on how FDA intends to address pharmacy compounding as a result of a recent decision by the Supreme Court.

DATES: Submit written or electronic comments on the guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Division of Compliance Policy (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Fred Richman, Center for Drug Evaluation and Research (HFD–330), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0101.

SUPPLEMENTARY INFORMATION:

I. Background

On March 16, 1992, FDA issued a CPG, section 460.200 (formerly CPG 7132.16), which delineated FDA's enforcement policy on pharmacy compounding. This CPG represented FDA's policy in this area until November 1997, when the President signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115). Section 127 of FDAMA added section 503A to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353a), which exempted compounded drug products from the requirements of sections 501(a)(2)(B) (current good manufacturing practices), 502(f)(1) (adequate directions for use), and 505 (new drug provisions) of the act (21 U.S.C. 351(a)(2)(B), 352(f)(1), and 355), provided that the compounding was conducted in accordance with and the drug products met the requirements in section 503A of the act.

In November 1998, the solicitation and advertising provisions of section