TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 088272	Thioridazine HCl Tablets USP, 25 mg	Do.
ANDA 088273	Thioridazine HCl Tablets USP, 100 mg	Do.
ANDA 088456	Thioridazine HCl Tablets USP, 100 mg	Teva Pharmaceuticals USA.
ANDA 088493	Thioridazine HCl Tablets USP, 10 mg	Do.
ANDA 088850	Hydroflumethiazide Tablets USP, 50 mg	Par Pharmaceutical, Inc.
ANDA 088907	Reserpine and Hydroflumethiazide Tablets, 0.125 mg/50 mg.	Do.
ANDA 088933	Sulfinpyrazone Tablets, 100 mg	Do.
ANDA 088934	Sulfinpyrazone Capsules USP, 200 mg	Do.
ANDA 089135	Methyclothiazide Tablets, 2.5 mg	Do.
ANDA 089136	Methyclothiazide Tablets, 5 mg	Do.
ANDA 089173	A–MethaPred (methylprednisolone sodium succinate for injection USP), 500 mg (base)/Vial.	Hospira, Inc.
ANDA 089174	A–MethaPred (methylprednisolone sodium succinate for injection USP), 1 gram (base)/Vial.	Do.
ANDA 089207	Methylprednisolone Tablets USP, 16 mg	Par Pharmaceutical, Inc.
ANDA 089208	Methylprednisolone Tablets USP, 24 mg	Do.
ANDA 089209	Methylprednisolone Tablets USP, 32 mg	Do.
ANDA 089457	Perphenazine Tablets USP, 16 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA.
ANDA 089602	Thioridazine HCl Oral Solution USP, 30 mg/mL	Teva Pharmaceuticals USA.
ANDA 089603	Thioridazine HCl Oral Solution USP, 100 mg/mL	Do.
ANDA 089624	Reversol (edrophonium chloride injection USP), 10 mg/mL).	Organon USA Inc.
ANDA 089657	Methocarbamol and Aspirin Tablets, 400 mg/325 mg	Par Pharmaceutical, Inc.
ANDA 089708	Perphenazine Tablets USP, 4 mg	Ivax Pharmaceuticals, Inc., Subsidiary of Teva Pharmaceuticals USA.

[1] This product included an oral pressurized metered-dose inhaler that contained chlorofluorocarbons (CFCs) as a propellant. CFCs may no longer be used as a propellant for any albuterol or salmeterol metered-dose inhalers (see 70 FR 17168, April 4, 2005; 71 FR 70870, December 7, 2006).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research, by the Commissioner, approval of the applications listed in table 1 in this document, and all amendments and supplements thereto, is hereby withdrawn, effective April 18, 2012. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the FD&C Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 in this document that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: February 16, 2012.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2012–6591 Filed 3–16–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (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 and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (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: Enrollment and Re-Certification of Entities in the 340B Drug Pricing Program (OMB No. 0915–0327)—Revision

Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act) ''Limitation on Prices of Drugs Purchased by Covered Entities.'' Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

Covered entities which choose to participate in the section 340B Drug Pricing Program must comply with the requirements of section 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate.

Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(9) of the PHS Act to notify manufacturers of the identities of covered entities and the mandate of section 340B(a)(5)(A)(ii) to establish a mechanism to ensure against duplicate discounts and the ongoing responsibility to administer the 340B Drug Pricing Program while maintaining efficiency, transparency and integrity, the HRSA Office of Pharmacy Affairs (OPA) developed a process of registration of covered entities to enable it to address those mandates.

Enrollment/Registration

To enroll and certify the eligible federally funded grantees and other safety net health care providers, OPA requires entities to submit administrative information (*e.g.,* shipping and billing arrangements, Medicaid participation), certifying information and signatures from appropriate grantee level or entity level authorizing officials and state/local government representatives. The purpose of this registration information is to determine eligibility for the 340B Drug Pricing Program. This information is entered into the 340B database by entities and verified by OPA staff according to 340B Drug Pricing Program requirements. Accurate records are critical to implementation of the 340B Drug Pricing Program, especially to prevent drug diversion to non-eligible individuals as well as duplicate discounts from manufacturers. To maintain accurate records, OPA also requires that entities recertify eligibility annually and that they notify the program of updates to any administrative information that they submitted when initially enrolling into the program. The burden requirement for these processes is low for recertification and minimal for submitting change requests.

Contract Pharmacy Self-Certification

In order to ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize one or more contract pharmacies are also required to submit general information about the arrangements and certifications that signed agreements are in place with those contract pharmacies.

The annual estimate of burden is as follows:

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Hospital Enrollment, Additions & Recertifications					
340B Program Registrations & Certifications for Hospitals	546	1	546	2.0	1092
Certifications to Enroll Hospital Outpatient Facilities	606	1	606	.50	303
Hospital Annual Recertifications	4842	1	4842	.50	2421
Registrations and Recertifications for Entities Other Than Hospitals					
340B Registrations for Community Health Centers	253	1	253	1.0	253
340B Registrations for Family Planning Programs, STD/TB Clinics and Various Other Eligible Entity Types	353	1	353	1.0	353
Community Health Center Annual Recertifications	4507	1	4507	.50	2253.5
Family Planning Annual Recertifications	3879	1	3879	.50	1939.5
STD & TB Annual Recertifications	2754	1	2754	.50	1377
Annual Recertification for Entities other than Hospitals, Community Health Centers, Family Planning, STD or TB Clinics	1174	1	1174	.50	587
Other Information Collections					
Submission of Administrative Changes for any Covered Entity	2500	1	2500	.50	1250
Submission of Administrative Changes for any Manufacturer	350	1	350	.50	175
Contracted Pharmacy Services Registration & Recertifications					
Contracted Pharmacy Services Registration	2500	1	2500	1.0	2500
Total	24,264		24,264		14,504

Email comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 13, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2012–6540 Filed 3–16–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Public Hearing

SUMMARY: The National Institutes of Health (NIH) will hold a public meeting on Thursday, April 19, 2012, from 6:30–9:30 p.m. at Roxbury Community College, Main Stage, 1234 Columbus Avenue, Boston, MA 02120. The