3014512521. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss and make recommendations on a premarket notification application for the ReGen Collagen Scaffold (CS), sponsored by ReGen Biologics, Inc. This device is intended for use in surgical procedures for the reinforcement and repair of chronic soft tissue injuries of the meniscus (one to three prior surgeries to the involved meniscus) where weakness exists. In repairing and reinforcing meniscal defects, the patient must have an intact meniscal rim and anterior and posterior horns for attachment of the mesh. In addition, the surgically prepared site for the CS must extend at least into the red/white zone of the meniscus to provide sufficient vascularization.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 7, 2008. Oral presentations from the public will be scheduled for 30 minutes at the beginning of the committee deliberations and for 30 minutes near the end of the deliberations. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 6, 2008. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 7, 2008.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Ann Marie Williams, Conference Management Staff, 240–276–8932, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.htm* for procedures on public conduct during advisory committee meetings.

FDA regrets that it was unable to publish this notice 15 days prior to the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 29, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–26230 Filed 10–30–08; 4:15 pm]

BILLING CODE 4160–01–S

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, e-mail *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer on (301) 443–1129.

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 (NEW)

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 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) 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 program. This information is received and verified according to 340B requirements and entered into the 340B database. Accurate records are critical to implementation of the 340B legislation especially to prevent diversion and duplicate discounts. To maintain accurate records, the OPA requests entities to submit modifications to any administrative information that they submitted when initially enrolling into the program. The burden requirement for these processes is minimal.

Recertification

The purposes of recertification are to request that 340B covered entities annually certify program eligibility and confirm the accuracy of all information in the covered entity's 340B database record. Recertification is an electronic process that will require the covered entity to review the current database record and submit required edits (i.e., covered entity name and address changes, changes to 340B designated contact information, billing and shipping arrangements). The recertification process will pose a minimal burden to 340B covered entities.

Contract Pharmacy Self-Certification

In order to ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize a contract pharmacy are required to submit to OPA a self-certification form similar to the registration form that they have signed an agreement with the contract pharmacy.

The estimates of annualized burden are as follows:

Reporting requirement	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
DSH & CHILDREN'S HOSPITAL ENROLLMENT, ADDITIONS & RECERTIFICATIONS					
340B Program Registrations & Certifications for Disproportionate Share Hospitals	70	1	70	.25	17.5
340B Program Registrations & Certifications for Children's Hospitals	80	1	80	.25	20
Certifications to Enroll DSH & Children's Hospitals Outpatient facilities to 340B Program	180	1	180	.083	14.94
DSH & Children's Hospitals' Annual Recertification	937	1	937	.5	468.5
REGISTRATION FOR ENTITIES OTHER THAN HOSPITALS & RECERTIFICATIONS					
340B Registration Form (Family Planning, STD, TB, and others)	170	1	170	.083	14.11
Family Planning Annual Recertification	85	47	3995	.083	331.59
STD & TB Annual Recertification	111	11	1221	.083	101.34
Other Entity Annual Recertification for entities other than DSHs, FP, STD or TB entities	400	10	4000	.083	332
Submission of Administrative Changes for any entity	460	1	460	.083	38.18
CONTRACTED PHARMACY SERVICES REGISTRATION & RECERTIFICATIONS					
Contracted Pharmacy Services Registration	2000	1	2000	.083	166
TOTAL	*4493		13,313		1504.16

*The total number of respondents may be overestimated since we are unable to avoid duplication of respondents who submit information to the OPA over the course of participation in the 340B Drug Pricing Program, via the initial registration process to any updates/modifications and enrolling contract pharmacies, if applicable, to the recertification process.

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: October 28, 2008.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E8–26271 Filed 11–3–08; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Meeting of the Advisory Council on Blood Stem Cell Transplantation

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of Meeting of the Advisory Council on Blood Stem Cell Transplantation.

SUMMARY: Pursuant to Public Law 92–463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the third meeting of the Advisory Council on Blood Stem Cell Transplantation (ACBSCT), Department of Health and Human Services (HHS). The meeting will be held from approximately 8:30 a.m. to 5 p.m. on December 15, 2008,