TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for reconsideration of a decision	5	1 time for each application	5	2	10
Request for review—(user fee appeal officer)	2	1 time for each application	2	2	4
Total					60

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

Based on FDA's database system, there are an estimated 250 sponsors of products subject to ADUFA. However, not all sponsors will have any submissions in a given year and some may have multiple submissions. The total number of waiver requests is based on the number of submission types received by FDA in fiscal year 2003. FDA's Center for Veterinary Medicine estimates 30 waiver requests that include the following: 5 significant barriers to innovation, 1 fee exceed cost, 5 free choice feeds, 10 minor use or minor species, 2 small business waiver requests, 5 requests for reconsideration of a decision, and 2 requests for user fee appeal officer. The estimated hours per response are based on past FDA experience with the various waiver requests in FDA's Center for Drug Evaluation and Research. The hours per response are based on the average of these estimates.

Dated: June 7, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–11425 Filed 6–13–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0221]

Otsuka Pharmaceutical Co., Ltd.; Withdrawal of Approval of a New Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for RAXAR (grepafloxacin hydrochloride (HCl)) Tablets held by Otsuka Pharmaceutical Co., Ltd. (Otsuka), c/o Otsuka Pharmaceutical Development & Commercialization, Inc., 2440 Research Blvd., Rockville, MD 20850. Otsuka has voluntarily requested that approval of this application be withdrawn because the product is no longer marketed, thereby waiving its opportunity for a hearing.

DATES: Effective June 14, 2007.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In a letter dated March 5, 2003, Otsuka requested that FDA withdraw approval of NDA 20–695 for RAXAR (grepafloxacin HC1) Tablets, stating that the product was no longer being marketed. In FDA's acknowledgment letter of June 20, 2003, the agency informed Otsuka that RAXAR (grepafloxacin HCl) Tablets, indicated for the treatment of a variety of infections, had been removed from the market because of safety concerns; in its follow-up letter of January 12, 2007, the agency also informed Otsuka that it had determined that the RAXAR NDA should be withdrawn under § 314.150(d) (21 CFR 314.150(d)) because of its effect on cardiac repolarization, manifested as QTc interval prolongation on the electrocardiogram, which could put patients at risk of Torsade de Pointes. In its letter of March 20, 2007, Otsuka concurred in the agency's determination to initiate withdrawal of the RAXAR NDA and waived its opportunity for a hearing, provided under 21 CFR 314.150(a) and (b).

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)), § 314.150(d), and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.105(a)), approval of the NDA 20–695, and all amendments and supplements thereto, is withdrawn, effective (see **DATES**). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the act (21 U.S.C. 331(d)).

Dated: May 31, 2007.

Douglas C. Throckmorton,

Deputy Director, Center for Drug Evaluation and Research.

[FR Doc. E7–11427 Filed 6–13–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 24, 2007, from 8 a.m. to 5 p.m.

Location: Advisors and Consultants Staff Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857.

Contact Person: Johanna Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6761, FAX: 301–827–6776, e-mail: *Johanna.Clifford@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512542. 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 the following new drug applications (NDAs): (1) NDA 022–042, EVISTA (raloxifene hydrochloride) Tablets, Eli Lilly and Co., proposed indications for the reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis, and for the reduction in risk of invasive breast cancer in postmenopausal women at high risk of breast cancer; and (2) NDA 021–801, proposed trade name ORPLATNA (satraplatin capsules), GPC Biotech Inc., proposed indication for the treatment of patients with androgen independent (hormone refractory) prostate cancer (HRPC) that has failed prior chemotherapy.

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 2007 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 July 10, 2007. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m. 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 July 2, 2007. 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 July 3, 2007.

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 Johanna Clifford at least 7 days in advance of the meeting.

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

Dated: June 6, 2007.

Randall W. Lutter,

Associate Commissioner for Policy and Planning.

[FR Doc. E7–11496 Filed 6–13–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Recruitment of Sites for Assignment of Corps Personnel

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: General notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that the listing of entities, and their Health Professional Shortage Area (HPSA) scores, that will receive priority for the assignment of National Health Service Corps (NHSC) personnel (Corps Personnel, Corps members) for the period July 1, 2007 through June 30, 2008 is posted on the NHSC Web site at *http://nhsc.bhpr.hrsa.gov/resources/fedreg-hpol/*. This list specifies which entities are eligible to receive assignment of Corps members who are participating in the NHSC Scholarship Program, the NHSC Loan Repayment Program, and Corps members who have become Corps members other than pursuant to contractual obligations under the Scholarship or Loan Repayment Programs. Please note that not all vacancies associated with sites on this list will be for Corps members, but could be for individuals serving an obligation to the NHSC through the Private Practice Option.

Eligible HPSAs and Entities

To be eligible to receive assignment of Corps personnel, entities must: (1) Have a current HPSA designation by the Shortage Designation Branch in the Office of Workforce Evaluation and Quality Assurance, Bureau of Health Professions, Health Resources and Services Administration; (2) enter into an agreement with the State agency that administers Medicaid, accept payment under Medicare and the State Children's Health Insurance Program, see all patients regardless of their ability to pay, and use and post a discounted fee plan; and (3) be determined by the Secretary to have (a) a need and demand for health manpower in the area; (b) appropriately and efficiently used Corps members assigned to the entity in the past; (c) general community support for the assignment of Corps members; (d) made unsuccessful efforts to recruit; and (e) a reasonable prospect for sound fiscal management by the entity with respect to Corps members assigned there. Priority in approving applications for assignment of Corps members goes to sites that (1) provide primary, mental, and/or oral health services to a HPSA of greatest shortage; (2) are part of a system of care that provides a continuum of services, including comprehensive primary health care and appropriate referrals or arrangements for secondary and tertiary care; (3) have a documented record of sound fiscal management; and (4) will experience a negative impact on its capacity to provide primary health services if a Corps member is not assigned to the entity.

Entities that receive assignment of Corps personnel must assure that (1) the position will permit the full scope of practice and that the clinician meets the credentialing requirements of the State and site; and (2) the Corps member assigned to the entity is engaged in full-time clinical practice at the approved service location for a minimum of 40 hours per week with at least 32 hours per week in the ambulatory care setting. Obstetricians/gynecologists, certified nurse midwives (CNMs), and family practitioners who practice obstetrics on a regular basis, are required to engage in a minimum of 21 hours per week of outpatient clinical practice. The remaining hours, making up the minimum 40-hour per week total, include delivery and other clinical hospital-based duties. For all Corps personnel, time spent on-call does not count toward the 40 hours per week. In addition, sites receiving assignment of Corps personnel are expected to (1) report to the NHSC all absences in excess of the authorized number of days