• Establishment type: Query has been made of CDRH's registration/listing databank and has counted 8,188 domestic firms subject to CGMPs. In addition, hospitals which reuse or remanufacture devices are now considered manufacturers under new FDA guidance. During the last report, it was estimated that out of the 6,000 hospitals in the United States, one third of them (or 2,000 hospitals) will reuse or remanufacture single use medical devices. After investigations of many hospitals and the changes in enforcements of FDA's requirements for hospitals, the number of reuse or remanufactures of single-use medical devices have decreased from the estimated 2,000 to an estimated 66 hospitals. Thus, the number of manufacturers will increase from 7,229 to 8,188, but the total number of firms subject to CGMPs will decrease from 9,229 to 8,254.

• Potentially affected establishments: Except for manufacturers, not every type of firm is subject to every CGMP/QS requirement. For example, all are subject to FDA's quality policy regulations (§ 820.20(a)), document control regulations (§ 820.40), and other requirements, whereas only manufacturers and specification developers are subject to FDA's design controls regulations (§ 820.30). The type of firm subject to each requirement was identified by ERG.

FDA estimated the burden hours (and costs) for the previous CGMP regulation in 1992. That estimate was submitted to OMB on May 4, 1992. It was approved by OMB on July 16, 1992, and expired on June 30, 1995. The methodology used is different than that used by ERG in estimating incremental tasks when the new CGMP/QS became final. Nevertheless, the agency believes its 1992 estimate adequately represents labor hours (and costs) needed to comply with previous CGMP requirements carried over into the new CGMP/QS regulation. The 1992 estimate used 9,289 respondents (rather than 8,254 respondents), which compensates for differences in methodology.

FDA estimates that some 650 ''new'' establishments (marketing devices for the first time) will expend some 143,052 ''development'' hours on a one-time startup basis to develop records and procedures for the CGMP/QS regulation.

FDA estimates that annual labor hours are apportioned as follows: 40 percent goes to requirements dealing with manufacturing specifications, process controls and the DHR; 20 percent goes to requirements dealing with components and acceptance activities; 25 percent goes to requirements dealing with equipment, records (the DMR and QSR), complaint investigations, labeling/packaging and reprocessing/investigating product nonconformance; and 15 percent goes to quality audit, traceability, handling, distribution, statistical, and other requirements.

Dated: February 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–3646 Filed 2–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004F–0066]

zuChem, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that zuChem, Inc. has filed a petition proposing that the food additive regulations be amended to permit the manufacture of mannitol by fermentation of sugars such as fructose, glucose, or maltose by the action of the microorganism *Lactobacillus intermedius* (*fermentum*).

FOR FURTHER INFORMATION CONTACT: Celeste Johnston, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 202–418–3423.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 4A4754) has been filed by zuChem Inc., c/o Hyman, Phelps and McNamara, P.C., 700 Thirteenth St. NW., Washington, DC 20005. The petition proposes to amend the food additive regulations in § 180.25 Mannitol (21 CFR 180.25) to permit the manufacture of mannitol by fermentation of sugars such as fructose, glucose, or maltose by the action of the microorganism *Lactobacillus intermedius* (*fermentum*).

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: February 9, 2004.

George H. Pauli,

Acting Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 04–3558 Filed 2–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Oncology Subcommittee of the 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: Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee.

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

Date and Time: The meeting will be held on March 17, 2004, from 8 a.m. to 5 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Johanna M. 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, 301–827–7001, FAX: 301–827–6776, e-mail: *cliffordj@cder.fda.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.

Agenda: The subcommittee will discuss the following topics: (1) Safety monitoring in clinical studies enrolling children with cancer, and (2) the use of nonclinical data to supplement clinical data for evaluation of cancer therapies.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by March 10, 2004. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11 a.m. and between