veterinary drug products. These products are all unapproved OTC products for use in nonfood species. For instance, older text books may contain an indication for red mercuric iodide petrolatum as a compounded counterirritant. An aqueous formulation of red mercuric iodide is commercially marketed with that indication. Mercurochrome is currently marketed for treating bacterial diseases of ornamental fish. The potential exists for some limited use of mercury compounds as inactive ingredients, such as preservatives, particularly in unapproved products.

IV. Mercury Compounds in Food Products

The agency has limited information on the intentional addition of mercury-containing compounds to food products. Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)), an ingredient used in food or as food must be an approved food additive or it must be GRAS for its intended food use. Currently, FDA has not approved any mercury-containing compounds as food additives and does not consider any mercury-containing compounds to be GRAS.

Substances that are ''dietary ingredients'' as defined in section 201(ff) of the act are exempt from the food additive provisions of the act under section 201(s)(6). Under the act, dietary supplement ingredients subject to section 201(ff) do not require FDA premarket scrutiny or approval. Additionally, ingredients subject to this section of the act do not need to be registered with FDA. Consequently, FDA has no listing of mercury-containing compounds that are used as dietary ingredients in dietary supplements.

The agency is aware that some categories of products marketed as dietary supplements in the United States may contain a source of added mercury. Products similar to those that are used as traditional medicines in other countries may sometimes be marketed as dietary supplements in the United States. For example, mercury-containing compounds are used in traditional Chinese medicines. The Chinese Herbal Materia Medica (Ref. 1) reports that cinnabar (mercuric sulfide; cinnabaris or zhu sha in Mandarin Chinese) and calomel (mercurous chloride; calomelas or qing fen in Mandarin Chinese) have been widely used as a sedative and detoxicant and to treat constipation and edema, respectively. The California Department of Health Services reported that 5 of 260 traditional Chinese medicines available in the retail marketplace, which they examined, listed cinnabar as an ingredient on the label (Ref. 2). In this study, 35 of 251 products that were screened for mercury content were found to contain significant quantities of mercury (Refs. 2 and 3). Additionally, the study showed that most of the products that contained significant quantities of mercury did not list mercury sources on the label. Therefore, it is not possible to determine whether the mercury in these products is intentionally added or is present as an unintended ingredient or contaminant. Other than this limited information, FDA is not aware of other uses of mercury in dietary supplements.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Bensky, D., A. Gamble, and T. Kaptchuk, *Chinese Herbal Medicine Materia Medica*, 8th Ed., Eastland Press, Inc., Seattle, pp. 573–574, 638–639, 1992.

2. Ko, R. J., and A. Au, *1997–1998 Compendium of Asian Patent Medicines*, California Department of Health Services, Food and Drug Branch, Sacramento, 1998.

3. Ko, R. J., ''Adulterants in Asian Patent Medicines,'' *New England Journal of Medicine*, 339:847, 1998.

VI. Call-for-Data and Information

In order to prepare the list and provide the analysis required by section 413 of FDAMA, the agency is requesting all manufacturers of any food, including dietary supplement, and human or veterinary drug product (prescription or OTC) containing any intentionally introduced mercury compounds, whether used as an active or inactive ingredient, to provide FDA the following information for each product:

1. The commercial name of the product that contains the mercury compound;

2. The chemical name (USAN or established name, if one exists) of the mercury compound(s) present in the drug product; the Chemical Abstract Service (CAS) registry (Reg.) number (No.) and the CAS preferred chemical name of the mercury compound(s) present in the food or dietary supplement product;

3. The quantitative amount of the mercury compound present in the product. State as either quantity per dosage unit or per quantity of product (e.g., ounce or gram). State whether amount is calculated on a weight to weight (w/w) or weight to volume (w/v) basis, where applicable;

4. State the purpose of the mercury compound in the product. If an active ingredient, state the pharmacologic use(s) of the product. If an inactive ingredient, state the function (e.g., preservative);

5. Provide a copy of the product's labeling; and

6. Estimate the amount of the mercury compound used annually in manufacturing the product.

VII. Request for Data and Information

Affected manufacturers should, on or before March 15, 1999, submit the data and information requested in section VI of this document. Two copies of the data and information are to be submitted, except that individuals may submit one copy. Data and information should be addressed to the appropriate FDA centers (Drug Evaluation and Research, Veterinary Medicine, or Food Safety and Applied Nutrition) (addresses above). All submitted data and information on the quantitative amount of the mercury compound present in the product (unless the information appears in product labeling) and the amount of the mercury compound used annually in manufacturing the product will be handled as confidential by the agency under 21 CFR 20.61. General comments on this call-for-data should be addressed to the Dockets Management Branch (address above). General comments are to be identified with the docket number found in brackets in the heading of this document. Received general comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 7, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–33053 Filed 12–11–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98F–1122]

GEO Specialty Chemicals; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that GEO Specialty Chemicals has filed a petition proposing that the food additive regulations be amended to provide for the safe use of

dimethylolpropionic acid as a pigment dispersant for pigments used as components of food-contact articles.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

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 9B4637) has been filed by GEO Specialty Chemicals, c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposes to amend the food additive regulations in § 178.3725 *Pigment dispersants* (21 CFR 178.3725) to provide for the safe use of dimethylolpropionic acid as a dispersant for pigments used as components of food-contact articles.

The agency has determined under 21 CFR 25.32(i) that this action is of the 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: December 1, 1998.

Laura M. Tarantino,

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

[FR Doc. 98–33055 Filed 12-11-98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Industry Training on Electronic Records; Electronic Signatures; Video Teleconferences; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) (Office of External Affairs, Office of Regulatory Affairs, Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health) is announcing the following meeting (video teleconferences) entitled ''Industry Training on 21 CFR Part 11.'' The topics to be discussed are current good manufacturing practice electronic recordkeeping requirements, validation of electronic recordkeeping systems, and the answers to frequently asked questions on part 11 (21 CFR part 11).

Date and Time: The meeting will be held on Tuesday, January 12, 1999, 1 p.m. to 4 p.m. Registration information should be faxed to the contact person listed in Table 1 of this document by January 8, 1999.

Contact Person: Laura C. Woolf, Office of Communications, Training and Manufacturers Assistance (HFM–40), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–3840, FAX 301–827–3843, e-mail address ''woolf@cber.fda.gov''.

SUPPLEMENTARY INFORMATION: These video teleconferences are intended to inform the FDA regulated industries, and especially, small business about the requirements for electronic recordkeeping according to part 11 and to provide for a dialogue with FDA. These video teleconferences address the requirements of both the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104–121) that mandates outreach activities by Government agencies directed to small businesses and section 406 (b) of The Food and Drug Administration Modernization Act of 1997 (Pub. L. No. 105–115) that calls for involvement of FDA with its stakeholders in cooperative activities to assure the quality of marketed products.

Location: The meeting (video teleconferences) will be held as follows:

TABLE 1.—PUBLIC MEETING (VIDEO TELECONFERENCES)

FDA Office/Region	Meeting Address	Time	Contact Person
Cincinnati District Office	6751 Steger Dr., Cincinnati, OH 45237	1 p.m. to 4 p.m., eastern standard time (e.s.t.)	Geraldine H. Cobb (HFR–MA430), Food and Drug Administration, 6751 Steger Dr., Cincinnati, OH 45237, 513–679–2700, ext. 100, FAX 513–679–2771
New Jersey District Office	10 Waterview Blvd., 3d Fl., Parsippany, NJ 07054	1 p.m. to 4 p.m., e.s.t.	Marie T. Falcone (HFR–SW17), Food and Drug Administration, 900 U.S. Customhouse, 2d & Chestnut Sts., Philadelphia, PA 19106, 215–597–4391, ext. 4003, FAX 215–597–5798
Chicago District Office	300 South Riverside Plaza, suite 500 South, Chicago, IL 60606	12 m. to 3 p.m., central standard time (c.s.t.)	Joe T. Petty (HFR–CE1), Food and Drug Administration, 20 North Michigan Ave., suite 510, Chicago, IL 60602, 312–353–9400, ext. 23, FAX 312–886–1682
Chicago-Central Region	20 North Michigan Ave., suite 510, Chicago, IL 60602	12 m. to 3 p.m., c.s.t.	Joe T. Petty (HFR–CE1), Food and Drug Administration, 20 North Michigan Ave., suite 510, Chicago, IL 60602, 312–353–9400, ext. 23, FAX 312–886–1682
Seattle District Office	22201 23d Dr. SE., Bothell, WA 98021	10 a.m to 1 p.m., Pacific standard time (P.s.t.)	Judy R. Keast (HFR–PA13), Food and Drug Administration, 1301 Clay St., suite 1180N, Oakland, CA 94612, 510–637–3960, ext.12, FAX 510–637–3976