issued export certificates. The new format may also help authenticate export certificates.

DATES: The agency will begin issuing export certificates using the new format after January 1, 1999.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION: Firms exporting products from the United States are often asked by foreign customers or foreign governments to supply a certification relating to products subject to the Federal Food, Drug, and Cosmetic Act (the act) and other FDA-administered acts. Certification is the process by which a formal or official attestation is made concerning a product's regulatory status or the system by which a commodity is manufactured. Certification does not show that FDA has ''approved'' the product for export; however, some certificates reflect that the product has been approved for marketing in the United States.

FDA currently issues several types of certificates. In brief, the principal certificates are:

1. Certificates to Foreign Government—used for products that may be legally marketed, sold, offered for sale, or distributed in the United States. For food products, these are commonly known as ''certificates of free sale'' or ''certificates of export.''

2. Certificates of Exportability—used for products that meet the requirements for export under section 801(e) or 802 of the act (21 U.S.C. 381(e) or 382)) but may not otherwise be marketed, sold, offered for sale, or distributed in the United States.

3. Certificates of a Pharmaceutical Product—used for pharmaceutical products and conform to the format in the World Health Organization's ''Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.''

FDA's Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, and Center for Veterinary Medicine receive and process requests for export certificates for products subject to their respective authorities.

Recently, there has been an increasing demand for export certificates, as well as requests from foreign governments to authenticate certificates and instances where FDA has found counterfeit or falsified certificates. Consequently, to facilitate the issuance and tracking of export certificates, deter unscrupulous persons from making counterfeit or false certificates or otherwise tampering with export certificates, and to help foreign governments identify authentic, FDA-issued export certificates more readily, FDA has adopted a new format for its export certificates. The new format features the use of several security measures in the paper used for export certificates.

FDA will begin using the new format on certificates issued after January 1, 1999. The procedures for requesting and issuing export certificates, as well as the text of the certificates themselves, will remain unchanged.

However, FDA will not use the new format on European Union (EU) Export Health Certificates. These certificates are for fishery products intended for import into the EU and are not considered to be FDA certificates.

FDA is notifying foreign embassies and its counterpart government agencies of the new format and also advising them that otherwise valid export certificates issued before January 1, 1999, remain valid. Consequently, persons whose export certificates were issued before January 1, 1999, but expire after that date, should not need to replace those certificates.

Dated: December 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–33052 Filed 12–11–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1109]

Mercury Compounds in Drugs and Food; Request for Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for data and information.

SUMMARY: The Food and Drug Administration (FDA) is announcing a call-for-data to identify food and drug products that contain intentionally introduced mercury compounds, e.g., mercurous chloride, mercuric chloride, phenylmercuric acetate, thimerosal. The agency is seeking both quantitative and qualitative information about the mercury compounds in these food and drug products. This request is part of the implementation of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit data and information by March 15, 1999. Submit written general comments by March 15, 1999.

ADDRESSES: Submit written general comments on this call-for-data to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit information on human drug products to the Division of Over-the-Counter (OTC) Drug Products (HFD–560), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit information on veterinary drug products to the Division of Epidemiology and Surveillance (HFV–210), Center for Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Submit information on food products, including dietary supplements, to the Office of Special Nutritionals (HFS–456), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

FOR FURTHER INFORMATION CONTACT:

For human drug products: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

For veterinary drug products: William C. Keller, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6641.

For food and dietary supplement products: Sharon A. Ross, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5343.

SUPPLEMENTARY INFORMATION:

I. Background

FDAMA (Pub. L. 105–115) was enacted on November 21, 1997. Section 413 of FDAMA, entitled ''Food and Drug Administration Study of Mercury Compounds in Drugs and Food,'' requires FDA to: (1) Compile a list of drugs and foods that contain intentionally introduced mercury compounds, and (2) provide a quantitative and qualitative analysis of the mercury compounds in this list. FDAMA requires the agency to compile the list and provide the analysis within 2 years after the date of its enactment. The statute does not differentiate

whether the mercury compound is present in the products as an active or an inactive ingredient. Therefore, FDA is requesting data and information on any mercury compounds, present as active or as inactive ingredients, in any human or veterinary drug (prescription or OTC) product or any food product, including dietary supplements.

II. Mercury Compounds in Human Drug Products

There are several different types of mercury compounds that have been used in human drug products. Inorganic mercury salts used include mercurous chloride (calomel) and mercuric chloride (bichloride of mercury). Organic aryl mercury compounds used include phenylmercuric acetate and phenylmercuric nitrate. Some of these mercury compounds (e.g., phenylmercuric acetate and phenylmercuric nitrate) have been used as both active and inactive ingredients. Some mercury-containing drug products have been marketed by prescription and others have been marketed OTC only.

FDA has already evaluated the safety and effectiveness of many of the OTC uses of mercury compounds as part of its OTC drug review. Many mercury compounds used as active ingredients in OTC drug products have been found to be not generally recognized as safe (GRAS) and effective and are classified as new drugs. These mercury ingredients are listed in § 310.545(a) (21 CFR 310.545(a)) (see Table 1 of this document).

TABLE 1.—MERCURY INGREDIENTS LISTED IN 21 CFR 310.545(a)

Rulemaking and Ingredients	Paragraph
Dandruff/seborrheic dermatitis/psoriasis drug products (Docket No. 82N–0214)	310.545(a)(7)
Mercury oleate	
External analgesic drug products: Poison ivy/poison oak/poison sumac drug products (Docket No. 78N–301P)	310.545(a)(10)(vii)
Merbromin (mercurochrome)	
Mercuric chloride (bichloride of mercury, mercury chloride)	
Laxative drug products: Stimulant laxatives (Docket No. 78N–036L)	310.545(a)(12)(iv)
Calomel (mercurous chloride)	
Skin bleaching drug products (Docket No. 78N–0065)	310.545(a)(17)
Mercury, ammoniated	
Skin protectant drug products: Poison ivy/poison oak/poison sumac drug products (Docket No. 78N–021P)	310.545(a)(18)(vi)
Merbromin (mercurochrome)	
Mercuric chloride (bichloride of mercury, mercury chloride)	
Ophthalmic drug products: Anti-infective (Docket No. 80N–0145)	310.545(a)(21)(ii)
Mercuric oxide, yellow	
First aid antiseptic drug products (Docket No. 75N–183F)	310.545(a)(27)(i)
Ammoniated mercury	
Calomel (mercurous chloride)	
Merbromin (mercurochrome)	
Mercufenol chloride (ortho-chloromercuriphenol, ortho-hydroxyphenylmercuric chloride)	
Mercuric chloride (bichloride of mercury, mercury chloride)	
Mercuric oxide, yellow	
Mercuric salicylate	
Mercuric sulfide, red	
Mercury	
Mercury oleate	
Mercury sulfide	
Nitromersol	
Para-chloromercuriphenol	
Phenylmercuric nitrate	
Thimerosal	
Vitromersol	
Zyloxin	
Antimicrobial diaper rash drug products (Docket No. 75N–183D)	310.545(a)(27)(ii)
Para-chloromercuriphenol	
Any other ingredient containing mercury	
Vaginal contraceptive drug products (Docket No. 80N–0280)	310.545(a)(28)
Phenylmercuric acetate	
Phenylmercuric nitrate	
Any other ingredient containing mercury	

FDA has also considered mercury compounds as inactive ingredients in OTC ophthalmic drug products. Section 349.50(c)(3) of the final monograph for OTC ophthalmic drug products (21 CFR 349.50(c)(3)) states:

For ophthalmic drug products containing mercury compounds used as a preservative. ''This product contains (name and quantity of mercury-containing ingredient) as a preservative. Do not use this product if you are sensitive to'' (select one of the following: ''mercury'' or ''(insert name of mercury-containing ingredient) or any other ingredient containing mercury).''

The agency is aware that mercury compounds (e.g., phenylmercuric acetate and thimerosal) are used as a preservative in OTC nasal solution products and prescription ophthalmic drug products. Phenylmercuric nitrate is also present in some oral homeopathic drug products and may be present in other homeopathic drug products. Therefore, homeopathic drug products are included in this call-for-data.

III. Mercury Compounds in Veterinary Drug Products

Currently, there are no approved veterinary drug products that contain a mercury compound as an active ingredient. There is some limited use, however, of mercury compounds in

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