and procedures must be posted near the processing equipment or made available to the operator (§ 113.87(a)).

Regulations in parts 108, 113, and 114 (21 CFR parts 108, 113, and 114) require firms to maintain records showing adherence to the substantive requirements of the regulations. These records must be made available to FDA on request. Firms are also required to document corrective actions when process controls and procedures do not fall within specified limits (§§ 113.89, 114.89, and 114.100(c)); to report any instance of potential health-endangering spoilage, process deviation, or contamination with microorganisms where any lot of the food has entered distribution in commerce (§§ 108.25(d) and 108.35(d) and (e)); and to develop and keep on file plans for recalling products that may endanger the public health (§§ 108.25(e) and 108.35(f)). To permit lots to be traced after distribution, acidified foods and thermally processed low-acid foods in hermetically sealed containers must be marked with an identifying code (§§ 113.60(c) (thermally processed foods), 114.80(b) (acidified foods)).

FDA estimates the burden of complying with the information collection provisions of the agency's regulations for acidified foods and thermally processed low-acid foods in hermetically sealed containers as follows:

Estimated Annual Reporting Burden

Form No.	CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
Form FDA 2541 (Registration)	108.25(c)(1) and 108.35(c)(1)	300	1	300	.17	51
Form FDA 2541a (Process Filing)	108.25(c)(2) and 108.35(c)(2)	1,000	6.5	6,500	.333	2,165
Form FDA 2541c (Process Filing)	108.35(c)(2)	1,000	.50	500	.75	375
	113.60(c)	?	?	?	?	?
	114.80(b)	?	?	?	?	?

Where question marks appear in the burden estimates, FDA does not have current information available. Public comments will be greatly appreciated.

Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Recordkeeper	Total Hours
21 CFR Parts 108, 113, 114	5,388	1	5,388	250	1,347,000

There are no capital or operating and maintenance costs associated with this collection.

The reporting burden for §§ 108.25(d) and 108.35(d) and (e) isinsignificant because notification of spoilage, process deviation, or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. To avoid double-counting, estimates for §§ 108.25(g) and 108.35(h) have not been included because they merely cross-reference recordkeeping requirements contained in parts 113 and 114.

Dated: May 1, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–11515 Filed 5–8–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96F–0139]

Bio-Cide International, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Bio-Cide International, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of acidified sodium chlorite solutions in processing water and ice which directly contact seafood such as finfish, shellfish, and crustaceans for the control of naturally occurring spoilage microorganisms to increase shelf life and to enhance seafood product freshness.

DATES: Written comments on the petitioner's environmental assessment by June 10, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204–0001, 202–418–3074.

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 6A4499) has been filed by Bio-Cide International, Inc., 2845 Broce Dr., Norman, OK 73072. The petition proposes to amend the food additive regulations in part 173 Secondary Direct Food Additives Permitted in Food for Human Consumption (21 CFR part 173) to provide for the safe use of acidified sodium chlorite solutions in processing water and ice which directly contact seafood such as finfish, shellfish, and crustaceans for the control of naturally occurring spoilage microorganisms to increase shelf life and to enhance

seafood product freshness.The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before June 10, 1996, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.40(c).

Dated: April 22, 1996.

George H. Pauli,

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

[FR Doc. 96–11512 Filed 5–8–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92F–0219]

Transcommerz AG; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 2B4325), filed by Transcommerz AG, proposing that the food additive regulations be amended to provide for the safe use of α-hydro-ω-hydroxypoly-(oxytetramethylene), diphenylmethane diisocyanate, 1,4-butanediol, ethylenediamine, 1,3-benzenedimethanamine, diethanolamine, and 1,3,5-tris(4-*tert*-butyl-3-hyroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)trione as components of a polyurethane elastomer; and dimethyl-polysiloxane, α-(ρ-nonylphenyl)-ω-hydroxypoly(oxyethylene), and parrafin oil as components of sizing and finishing oils for the polyurethane elastomer in food-contact articles used in the processing and packaging of food, including meat and poultry.

FOR FURTHER INFORMATION CONTACT: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 9, 1992 (57 FR 30496), FDA announced that a food additive petition (FAP 2B4325) had been filed by Transcommerz AG, c/o 7300 West Camino Real, Boca Raton, FL 33433. The petition proposed to amend the food additive regulations to provide for the safe use of α-hydro-ω-hydroxypoly-(oxytetramethylene), diphenylmethane diisocyanate, 1,4-butanediol, ethylenediamine, 1,3-benzenedimethanamine, diethanolamine, and 1,3,5-tris(4-*tert*-butyl-3-hyroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)trione as components of a polyurethane elastomer; and dimethyl-polysiloxane, α-(ρ-nonylphenyl)-ω-hydroxypoly(oxyethylene), and parrafin oil as components of sizing and finishing oils for the polyurethane elastomer in food-contact articles used in the processing and packaging of food, including meat and poultry. Transcommerz AG has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: April 23, 1996.

Eugene C. Coleman,

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

[FR Doc. 96–11513 Filed 5–8–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95S–0181]

U.S.–European Union Mutual Recognition Agreement Activities; Pharmaceutical GMP's and Medical Devices; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a public docket through which it will make available information concerning its participation in bilateral Mutual Recognition Agreement (MRA) talks in the areas of pharmaceutical GMP's and medical devices being led by the Office of the U.S. Trade Representative (USTR) and the Department of Commerce (DOC) and by representatives of the European Commission.

ADDRESSES: Documents concerning FDA's bilateral MRA talks are available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Walter M. Batts, Office of International Affairs (HFY–50), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4480.

SUPPLEMENTARY INFORMATION: The U.S. Government, led by USTR and DOC, is engaged in formal talks with the European Union (EU), led by Directorate-General I (External Relations) of the European Commission. The EU initiated these talks to facilitate access to foreign markets for their products and to facilitate access to the EU market for foreign products. The EU indicated that the latter purpose was in response to concerns raised by foreign countries, including the United States, that the ''Single Internal Market by 1992'' program would result in a ''fortress Europe'' that would disadvantage foreign firms. The EU is also pursuing separate MRA talks with other countries, including Canada, Australia, and Japan.

As a result of an EU request to identify products to be covered by the MRA talks and their proposal that pharmaceuticals and medical devices be included, the U.S. Government with support by the industry agreed that pharmaceuticals, GMP's, and medical devices should be among those areas included in the talks. FDA's discussions with the EU cover GMP's for human and animal drugs, human biologicals, and medical devices.

In 1989, prior to the initiation of the MRA talks by Directorate-General I, USTR, and DOC, FDA and Directorate-General III (Industrial Affairs) of the European Commission decided to begin discussions that may lead to an agreement in the pharmaceutical good manufacturing practices (GMP's) and medical devices area. FDA's primary motivation in seeking such an agreement was at that time, and still is, a desire to most effectively utilize limited resources. FDA recognized the