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

value of pursuing such agreements with selected foreign regulatory bodies in its 1992 ''Report of the Task Force on International Harmonization.'' The task force concluded that the development of memoranda of understanding (MOU's) is an effective means of facilitating international harmonization; of ensuring the safety, efficacy, and/or quality of products that are offered for import into the United States; and of efficiently using agency inspectional resources. The task force, however, cautioned that the negotiation of MOU's must be with foreign regulatory agencies that have appropriate authority and expertise to ensure the proper implementation of any MOU that may be agreed upon. A properly conceived and executed agreement with the European Commission would permit the use of EU Member State government inspectional information to assist FDA in its regulatory decisionmaking and could help to set priorities for foreign inspection or import surveillance programs. Early initiatives to pursue an MOU with the European Commission did not receive high priority by either side. Recently the MRA talks have served as a catalyst for reinvigorating these discussions.

The talks have been led by USTR and DOC with the Directorate-General I as their counterpart office in the European Commission. There have been six rounds of talks to date, beginning in April 1994. The most recent round of talks was held in Washington, DC, from November 13 through 15, 1995. FDA has participated in each round of discussions.

To provide an opportunity for public input into the pharmaceutical GMP discussions with the European Commission and the Member States, FDA hosted a public exchange meeting on March 31, 1995. The meeting was attended by approximately 40 persons representing the drug and biologics industries, consultants, and other organizations. Attendees expressed support for, as well as concerns regarding, the proposed agreement.

A delegation of FDA officials attended a pharmaceutical GMP workshop hosted by the European Commission in Brussels from April 3 to 5, 1995. The purpose of the meeting was to exchange information on inspection programs in the United States and the EU, and how each of the EU Member States carries out its role. The Canadian Health Protection Branch also attended the meeting and made a presentation on their pharmaceutical GMP program. At the conclusion of the workshop it was agreed that further cooperative efforts are needed before we could develop an MRA or MOU. Such efforts could include exchange of inspection reports, joint inspections, joint training of inspectors, and development of a joint inventory of facilities requiring inspection.

Also, following the conclusion of the workshop, industry representatives from the EU and the United States were invited to express their views. Both sides expressed support for an agreement. The U.S. pharmaceutical industry generally expressed the desire for a harmonized approach. The EU pharmaceutical industry expressed a desire for an approach that provided for mutual recognition of the current systems.

On May 1, 1995, a delegation of FDA officials also participated in meetings with EU officials and notified body representatives to allow both sides to better understand their respective medical device regulatory regimes. In addition to useful exchange of information and ''confidence building,'' the meetings helped to clarify several technical issues related to an MRA on medical devices.

Through this notice, FDA is establishing a public docket in order to make available at a convenient location certain information concerning its participation in these bilateral MRA talks. Information currently contained in this public docket includes the following:

Minutes of the FDA-sponsored public exchange meeting held on March 31, 1995.

Agenda of FDA-sponsored public exchange meeting held on March 31, 1995.

Statements of participants presented at the FDA-sponsored public exchange meeting held on March 31, 1995.

Summary of the April 3 through 5, 1995, Pharmaceutical GMP Workshop in Brussels.

Summary of the July 10 through 12, 1995, MRA talks in Brussels concerning pharmaceutical GMP's.

FDA summary of November 13 through 15, 1995, round of negotiations.

Presentation of Walter Batts entitled ''Mutual Recognition Agreement Negotiations with EU re: Pharmaceutical GMP's-FDA's Perspective,'' February 13, 1996.

Dated: May 1, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–11517 Filed 5–8–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[MB–098–N]

Medicaid Program; Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1996

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the preliminary Federal fiscal year (FFY) 1996 national target and individual State allotments for Medicaid payment adjustments made to hospitals that serve a disproportionate number of Medicaid recipients and low-income patients with special needs. We are publishing this notice in accordance with the provisions of section 1923(f)(1)(C) of the Social Security Act and implementing regulations at 42 CFR 447.297 through 447.299. The preliminary FFY 1996 State disproportionate share hospital (DSH) allotments published in this notice will be superseded by final FFY 1996 DSH allotments to be published in the Federal Register subsequent to the publication of this notice.

EFFECTIVE DATE: The preliminary DSH payment adjustment expenditure limits included in this notice apply to Medicaid DSH payment adjustments that are applicable to FFY 1996.

FOR FURTHER INFORMATION CONTACT: Richard Strauss, (410) 786–2019.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1902(a)(13)(A) of the Social Security Act (the Act) requires States to ensure that their Medicaid payment rates include payment adjustments for Medicaid-participating hospitals that serve a large number of Medicaid recipients and other low-income individuals with special needs (referred to as disproportionate share hospitals (DSHs)). The payment adjustments are calculated on the basis of formulas specified in section 1923 of the Act.

Section 1923(f) of the Act and implementing Medicaid regulations at 42 CFR 447.297 through 447.299 require us to estimate and publish in the Federal Register the national target and each State's allotment for DSH payments for each Federal fiscal year (FFY). The implementing regulations provide that the national aggregate DSH limit for a FFY specified in the Act is a target rather than an absolute cap when determining the amount that can be allocated for DSH payments. The national DSH target is 12 percent of the total amount of medical assistance