that Bayer Co. has filed a petition proposing that the food additive regulations be amended both to provide for the safe use of dimethyl dicarbonate (DMDC) in noncarbonated juice beverages containing up to and including 100 percent juice and to also provide for a more descriptive term, in place of ''inhibitor of yeast'', for the safe use of DMDC.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3077.

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 0A4718) has been filed by Bayer Co., c/o McKenna & Cuneo LLP, 1900 K St., NW., Washington, DC 20006–1108. The petition proposes to amend the food additive regulations in § 172.133 *Dimethyl dicarbonate* (21 CFR 172.133) both to provide for the safe use of DMDC in noncarbonated juice beverages containing up to and including 100 percent juice and also to provide for a more descriptive term, in place of ''inhibitor of yeast'', for the safe use of DMDC.

The agency has determined under 21 CFR 25.32(k) and 21 CFR 25.30(i) 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 22, 2000.

Alan M. Rulis,

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

[FR Doc. 00–5468 Filed 3–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00F–0813]

Tritex Co., Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Tritex Co., Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of sodium xylene sulfonated as a component of paper and paperboard intended to contact food.

FOR FURTHER INFORMATION CONTACT: Mark Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

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 0B4719) has been filed by Tritex Co., Inc., 1001 Boul. Industriel, Saint-Eustache (Quebec), CANADA J7H 6C3. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of sodium xylene sulfonated as a component of paper and paperboard intended to contact food.

The agency has determined under 21 CFR 25.32(i) 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 22, 2000.

Alan M. Rulis,

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

[FR Doc. 00–5419 Filed 3–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–0018]

Orthopedic Devices; Reclassification of the Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented Prosthesis and the Knee Joint Femorotibial (Uni-compartmental) Metal/Polymer Porous-Coated Uncemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is announcing for public comment two recommendations of the Orthopedic and Rehabilitation Devices Panel (the Panel) to reclassify the knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis and the knee joint femorotibial (uni-compartmental) metal/polymer porous-coated uncemented prosthesis from class III into class II. The Panel made these recommendations after reviewing the reclassification petition submitted by the Orthopedic Surgical Manufacturers Association (OSMA) and other publicly available information. FDA is also announcing for public comment its tentative findings on the Panel's recommendations. After considering any public comments on the Panel's recommendations and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the reclassification petition will be announced in the **Federal Register**.

DATES: Submit written comments by June 7, 2000.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Peter G. Allen, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most