(Organon), and was initially approved on October 5, 1962. Under the Drug Efficacy Study Implementation (DESI), FDA concluded that nandrolone decanoate was effective for the indications described in the **Federal Register** notice published on July 15, 1983 (DESI 7630, 48 FR 32394). DECA-DURABOLIN is an anabolic steroid indicated for the management of the anemia of renal insufficiency and has been shown to increase hemoglobin and red cell mass. Organon notified FDA in a letter dated May 21, 2002, that it was no longer marketing DECA-DURABOLIN (nandrolone decanoate) Injection, 200 mg/mL, 1 mL, and the drug product was moved to the "Discontinued Drug Product List" section of the Orange Book. PharmaForce, Inc., submitted a citizen petition dated May 7, 2009 (Docket No. FDA–2009–P–0218), under 21 CFR 10.30 requesting that the agency determine whether DECA-DURABOLIN (nandrolone decanoate) Injection, 200 mg/mL, 1 mL, was withdrawn from sale for reasons of safety or effectiveness.

FDA has reviewed its records and, under § 314.161, has determined that DECA-DURABOLIN (nandrolone decanoate) Injection, 200 mg/mL, 1 mL, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that DECA-DURABOLIN (nandrolone decanoate) Injection, 200 mg/mL, 1 mL, was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list DECA-DURABOLIN (nandrolone decanoate) Injection, 200 mg/mL, 1 mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DECA-DURABOLIN (nandrolone decanoate) Injection, 200 mg/mL, 1 mL, may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for this drug product should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: August 5, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19698 Filed 8–9–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0391]

Determination That MOTRIN (Ibuprofen) Tablets and Four Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the five drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, a drug is withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicant, FDA withdrew approval of NDA 18–354 for ORTHO–NOVUM 10/11–21 and 10/11–28 (ethinyl estradiol; norethindrone) Tablets in the **Federal Register** of February 11, 2009 (74 FR 6896).)

Application No.	Drug	Applicant
NDA 17–463	MOTRIN (ibuprofen) Tablets, 300 milligrams (mg), 400 mg, 600 mg, and 800 mg	McNeil Consumer Healthcare, 7050 Camp Hill Rd., Fort Washington, PA 19034
NDA 18–303	LOPRESSOR HCT (hydrochlorothiazide; metoprolol tartrate) Tablets, 50 mg; 100 mg	Novartis Pharmaceuticals Corp., 59 Rte. 10, East Hanover, NJ 07936–1080

Application No.	Drug	Applicant
NDA 18–354	ORTHO-NOVUM 10/11–21 and 10/11–28 (ethinyl estradiol; norethindrone) Tablets, 0.035 mg, 0.035 mg; 0.5 mg, 1 mg	Ortho McNeil Janssen Pharmaceuticals, Inc., 1125 Trenton Harbourton Rd., Titusville, NJ 08560
NDA 18–423	HIBICLENS (chlorhexidine gluconate) Topical Sponge, 4 %	Molnycke Health Care, 5550 Peachtree Parkway, Ste. 500, Norcross, GA 30092
NDA 19–436	PRIMACOR (milrinone lactate) Injection, Equivalent to (EQ) 1 mg base/milliliter	Sanofi Aventis U.S. LLC, 55 Corporate Dr., Bridgewater, NJ 08807

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: July 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19638 Filed 8–9–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–F–0320]

United States Pharmacopeial Convention; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the U.S. Pharmacopeial Convention has filed a petition proposing that the food additive regulations that incorporate by reference food-grade specifications from prior editions of the Food Chemicals Codex (FCC) be amended to incorporate by reference food-grade specifications from the FCC, 7th Edition.

FOR FURTHER INFORMATION CONTACT: Mical E. Honigfort, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1278.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 0A4782) has been filed by U.S. Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852. The petition proposes that the food additive regulations in table 1 of this document, which incorporate by reference food-grade specifications from prior editions of the FCC, be amended to incorporate by reference food-grade specifications from the FCC, 7th Edition.

TABLE 1.—LIST OF REGULATIONS

21 CFR Section	FCC Edition and/or Supplement Currently Referenced	Name of Additive	Current FCC Reference
172.167(b)	6th Ed.	Hydrogen peroxide	Meets FCC specifications.
172.320(b)(1)	3d Ed.	Amino acids	Meets FCC specifications.
172.345(b)	4th Ed.	Folic acid (folacin)	Meets FCC specifications.
172.379(b)	6th Ed.	Vitamin D_2	Meets FCC specifications.
172.380(b)	5th Ed.	Vitamin D_3	Meets FCC specifications.
172.665(d)(2)	4th Ed.	Gellan gum	Residual isopropyl alcohol limit not to exceed 0.075% by the procedure described in the Xanthan Gum monograph.
172.712(b)	4th Ed.	1,3-Butylene glycol	Conforms to FCC identity and specifications.
172.723(b)(3)	4th Ed.	Epoxidized soybean oil	Heavy metals (as lead) content cannot be more than 10 parts per million (ppm) as determined by the "Heavy Metals Test."
172.736(b)(2)	5th Ed.	Glycerides and polyglycides of hydrogenated vegetable oils	Acid value not greater than 2, and hydroxyl value, not greater than 56 as determined by "Acid Value" and "Hydroxyl Value" methods.