TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
106.100	5	10	50	400	20,000
107.50(c)(3)	3	10	30	300	9,000
Total					29,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3.—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency of Disclosure	Total Annual Disclosures	Hours per Disclosure	Total Hours
107.10(a) and 107.20	5	13	65	8	520

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In compiling these estimates, FDA consulted its records of the number of infant formula submissions received in the past. All infant formula submissions to FDA may be provided in electronic format. The hours per response reporting estimates are based on FDA's experience with similar programs and information received from industry.

FDA estimates that it will receive 13 reports from 5 manufacturers annually under section 412(d) of the act, for a total annual response of 65 reports. Each report is estimated to take 10 hours per response for a total of 650 hours. FDA also estimates that it will receive one notification under § 106.120(b). The notification is expected to take 4 hours per response, for a total of 4 hours.

For exempt infant formula, FDA estimates that it will receive 2 reports from 3 manufacturers annually under §§ 107.50(b)(3) and (b)(4), for a total annual response of 6 reports. Each report is estimated to take 4 hours per response for a total of 24 hours. FDA also estimates that it will receive one notification under § 107.50(e)(2). The notification is expected to take four hours per response, for a total of four hours.

FDA estimates that 5 firms will expend approximately 20,000 hours per year to fully satisfy the recordkeeping requirements in § 106.100. It is estimated that 3 firms will expend approximately 9,000 hours per year to fully satisfy the recordkeeping requirements in § 107.50(c)(3).

FDA estimates that compliance with the labeling requirements of §§ 107.10(a) and 107.20 will require 520 hours annually by 5 manufacturers.

Dated: August 5, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–19640 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–2009–P–0218]

Determination That DECA-DURABOLIN (Nandrolone Decanoate) Injection, 200 Milligrams/Milliliter, 1 Milliliter, Was 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) is announcing its determination that DECA-DURABOLIN (nandrolone decanoate) Injection, 200 milligrams/milliliter (mg/mL), 1 mL, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for nandrolone decanoate, 200 mg/mL, 1 mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6312, 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 (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 known generally as the "Orange Book." Under FDA regulations, drugs are removed 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 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

DECA-DURABOLIN (nandrolone decanoate) Injection is the subject of NDA 13–132, held by Organon, Inc.

(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