TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
210 and 211	285	1	285	.25	71.25
Total	285	1	285	.25	71.25

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

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: February 29, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–4474 Filed 3–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0130]

Determination That RELAFEN (Nabumetone) Tablets and Three Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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The Food and Drug Administration (FDA) has determined that the four drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness.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 the 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 A. 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 sponsors 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. Sponsors of ANDAs 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, drugs are 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 or (2) whenever a listed drug is voluntarily withdrawn from sale, and ANDAs that refer to the listed drug have been approved. Section 314.161(d) provides that if FDA determines that a listed drug was removed from sale for safety or effectiveness reasons, 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.

NDA No.	Drug	Applicant
19–583	RELAFEN (nabumetone) Tablets, 500 milligrams (mg) and 750 mg	GlaxoSmithKline (formerly SmithKlineBeecham), 2301 Renaissance Blvd., P.O. Box 161540, King of Prussia, PA 19406–2772
19–643	MEVACOR (lovastatin) Tablets, 10 mg	Merck & Co., One Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889–0100
50–416	CORTISPORIN Ophthalmic Ointment (bacitracin zinc; hydrocortisone; neomycin sulfate; polymyxin B sulfate) 400 units/gram (g); 1 percent; equivalent to 3.5 mg base/g; 10,000 units/g	Monarch Pharmaceuticals, Inc., 501 Fifth Street, Bristol, TN 37620
50–461	ANCEF (cefazolin sodium) Injection, 250 mg base/vial, 500 mg base/vial, 5 g base/vial	GlaxoSmithKline

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 for the 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: February 29, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–4469 Filed 3–6–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0142]

Draft Guidance for Industry and Review Staff on Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and review staff entitled ''Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route.'' The draft guidance provides recommendations concerning development of safety profiles to support approval of reformulated drug products and products proposed for use by a route of administration for which the product was not previously approved.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by May 6, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paul Brown, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5172, Silver Spring, MD 20993–0002, 301–796–0856.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and review staff entitled ''Nonclinical Safety Evaluation of Reformulated Drug Products and Products Intended for Administration by an Alternate Route.'' This draft guidance is intended for individuals or organizations and review staff in the Center for Drug Evaluation and Research involved in the development and review of new formulations of products containing previously approved drug substances and proposals for existing formulations to be used in a new route of administration. This draft guidance assumes that the drug substance has already been used in an approved drug product. It outlines the nonclinical information generally recommended to support the development of a new formulation containing a previously approved drug substance.

This draft guidance also provides nonclinical evaluation information for formulations intended for use by new routes of administration even if there is no change in the composition of the formulation. Although this situation does not represent a reformulation, it is appropriate in this case to reevaluate the toxicity information using considerations outlined in the draft guidance.

This draft guidance does not absolve the sponsor from providing complete nonclinical information for a drug product, either directly or through a right of reference to such information or by relying on the finding of safety and effectiveness for a listed drug and establishing a clinical bridge to that listed drug. This draft guidance pertains to new formulations containing previously approved drug substances only and does not address the safety evaluation of excipients.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the safety evaluation of reformulated drug products, including products intended for administration by an alternate route. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: February 29, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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