Administrative Simplification provisions.

- Develops and implements an outreach program for HIPAA Administrative Simplification provisions. Formulates and coordinates a public relations campaign, prepares and delivers presentations and speeches, responds to inquiries on HIPAA issues, and maintains liaison with industry representatives.
- Adopts and maintains messaging and vocabulary standards supporting electronic prescribing under Medicare Part D.
- Serves as agency point of reference on Federal and private sector e-health initiatives. Works with Federal departments and agencies to identify and adopt universal messaging and clinical health data standards, and represents CMS and HHS in national projects supporting the national health enterprise architecture and the national health information infrastructure.
- Coordinates and provides guidance on legislative and regulatory issues related to e-health standards and services.
- Collaborates with HHS on policy issues related to e-health standards, and serves as the central point of contact for the Office of the National Coordinator for Health Information Technology.
- Oversees the development of privacy and confidentiality policies pertaining to the collection, use, and release of individually identifiable data.

Dated: October 19, 2007.

Karen Pelham O'Steen,

Director, Office of Operations Management, Centers for Medicare & Medicaid Services.

Editorial Note: This document was received at the Office of the Federal Register on Tuesday, March 4, 2008.

[FR Doc. E8–4585 Filed 3–6–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0146]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements for Collection of Data Relating to the Prevention of Medical Gas Mix-ups at Health Care Facilities-Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on measures, taken by certain health care medical facilities that use medical oxygen, to present mix-ups with other gases.

DATES: Submit written or electronic comments on the collection of information by May 6, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Requirements for Collection of Data Relating to the Prevention of Medical Gas Mix-ups at Health Care Facilities-Survey—(OMB Control Number 0910–0548)—Extension

FDA has received four reports of medical gas mix-ups occurring during the past 9 years. These reports were received from hospitals and nursing homes and involved 7 deaths and 15 injuries to patients who were thought to be receiving medical grade oxygen, but who were actually receiving a different gas (e.g., nitrogen, argon) that had been mistakenly connected to the facility's oxygen supply system. In 2001, FDA published guidance making recommendations to help hospitals, nursing homes, and other health care facilities avoid the tragedies that result from medical gas mix-ups and alerting these facilities to the hazards. This survey is intended to assess the degree of facilities' compliance with safety measures to prevent mix-ups, to determine if further steps are warranted to ensure the safety of patients.

FDA estimates the burden of this collection of information as follows:

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