3. Verify match findings before reducing, suspending, or terminating an individual's benefits or payments;

4. Furnish detailed reports to Congress and OMB; and

5. Establish a Data Integrity Board that must approve matching agreements.

This Computer Match meets the requirements of Pub. L. 100–503.

Dated: March 22, 2005.

David H. Siegel,

Acting Commissioner, Office of Child Support Enforcement.

Notice of Computer Matching Program

A. Participating Agencies

OCSE and IMA.

B. Purpose of the Match

To exchange personal data for purposes of identifying individuals who are employed and also are receiving payments pursuant to TANF benefit programs being administered by the IMA and to verify continuing eligibility for TANF benefits.

OCSE will match public assistance records, obtained from IMA, to the NDNH. After matching has been conducted, OCSE will provide matched data to IMA which will use this information to verify the continued eligibility of individuals to receive public assistance benefits and, if ineligible, to take such action, as may be authorized by law and regulation. Under the matching program, IMA will obtain data provided by OCSE.

C. Authority for Conducting the Match

The authority for conducting the matching program is contained in section 453(j)(3) of the Social Security Act (42 U.S.C. 653(j)(3)).

D. Records To Be Matched

The system of records maintained by the ACF under the Privacy Act of 1974, as amended, 5 U.S.C. 552a, from which records will be disclosed for the purpose of this computer match, is the Location and Collection System of Records, DHHS/OCSE No. 09–90–0074, last published in the **Federal Register** at 69 FR 31392 on June 3, 2004. The match is a routine use under this system of records.

OCSE, as the source agency, will collect from IMA electronic files containing the names and other personal identifying data of eligible public assistance beneficiaries. Upon receipt of the electronic files of IMA beneficiaries, OCSE will perform a computer match against the NDNH. The NDNH database consists of Quarterly Wage, New Hire, and Unemployment Insurance information. The matches will be furnished by OCSE to IMA.

1. The electronic files provided by IMA will contain data elements of the client's name and SSN.

2. OCSE will match the SSN on the IMA file by computer against the NDNH database. Matching records, based on SSNs, will produce data elements of the individual's name; SSN; employer, and current work or home address, etc.

E. Inclusive Dates of the Matching Program

The effective date of the matching agreement and date when matching may actually begin shall be at the expiration of the 40-day review period for OMB and Congress, or 30 days after publication of the matching notice in the **Federal Register**, whichever date is later. By agreement between DHHS and IMA, the matching program will be in effect for 18 months from the effective date, with an option to renew for 12 additional months, unless one of the parties to the agreement advises the other by written request to terminate or modify the agreement.

[FR Doc. 05–6056 Filed 3–25–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0100]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals

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 the information collection provisions of FDA's current good manufacturing practice (CGMP) regulations for finished pharmaceuticals.

DATES: Submit written or electronic comments on the collection of information by May 27, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. 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: Karen Nelson, Office of Management Programs (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.

CGMP Regulations for Finished Pharmaceuticals—21 CFR Parts 210 and 211 (OMB Control Number 0910–0139)—Extension

Under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(a)(2)(B)), a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in conformity with, CGMPs to ensure that such drug meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

FDA has the authority under section 701(a) of the act (21 U.S.C. 371(a)) to issue regulations for the efficient enforcement of the act regarding CGMP procedures for manufacturing, processing, and holding drugs and drug products. The CGMP regulations help ensure that drug products meet the statutory requirements for safety and have their purported or represented identity, strength, quality, and purity characteristics. The information collection requirements in the CGMP regulations provide FDA with the necessary information to perform its duty to protect public health and safety. CGMP requirements establish accountability in the manufacturing and processing of drug products, provide for meaningful FDA inspections, and enable manufacturers to improve the quality of drug products over time. The CGMP recordkeeping requirements also serve preventive and remedial purposes, and provide crucial information if it is necessary to recall a drug product.

The general requirements for recordkeeping under part 211 (21 CFR part 211) are set forth in § 211.180. Any production, control, or distribution record associated with a batch and required to be maintained in compliance with part 211 must be retained for at least 1 year after the expiration date of the batch and, for certain over-the-counter (OTC) drugs, 3 years after distribution of the batch (§ 211.180(a)). Records for all components, drug product containers, closures, and labeling are required to be maintained for at least 1 year after the expiration date and 3 years for certain OTC products (§ 211.180(b)).

All part 211 records must be readily available for authorized inspections during the retention period (§ 211.180(c)), and such records may be retained either as original records or as true copies (§ 211.180(d)). In addition, 21 CFR 11.2(a) provides that ''for records required to be maintained but not submitted to the agency, persons may use electronic records in lieu of paper records or electronic signatures in lieu of traditional signatures, in whole or in part, provided that the requirements of this part are met.'' To the extent this electronic option is used, the burden of maintaining paper records should be substantially reduced, as should any review of such records.

In order to facilitate improvements and corrective actions, records must be maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures (§ 211.180(e)). Written procedures for these evaluations are to be established and include provisions for a review of a representative number of batches and, where applicable, records associated with the batch; provisions for a review of complaints, recalls, returned or salvaged drug products; and investigations conducted under § 211.192 for each drug product.

The specific recordkeeping requirements provided in table 1 of this document are as follows:

- Section 211.34—Consultants advising on the manufacture, processing, packing, or holding of drug products must have sufficient education, training, and experience to advise on the subject for which they are retained. Records must be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.
- Section 211.67(c)—Records must be kept of maintenance, cleaning, sanitizing, and inspection as specified in §§ 211.180 and 211.182.
- Section 211.68—Appropriate controls must be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.
- Section 211.68(a)—Records must be maintained of calibration checks, inspections, and computer or related system programs for automatic, mechanical, and electronic equipment.
- Section 211.68(b)—All appropriate controls must be exercised over all computers or related systems and control data systems to assure that changes in master production and controls records or other records are instituted only by authorized persons.
- Section 211.72—Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use must not release fibers into such products.
- Section 211.80(d)—Each container or grouping of containers for components or drug product containers or closures must be identified with a distinctive code for each lot in each shipment received. This code must be used in recording the disposition of each lot. Each lot must be appropriately identified as to its status.
- Section 211.100(b)—Written production and process control procedures must be followed in the execution of the various production and process control functions and must be documented at the time of performance. Any deviation from the written procedures must be recorded and justified.
- Section 211.105(b)—Major equipment must be identified by a distinctive identification number or code that must be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the name of the equipment may be used in lieu of a distinctive identification number or code.
- Section 211.122(c)—Records must be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination, or testing.
- Section 211.130(e)—Inspection of packaging and labeling facilities must be made immediately before use to assure that all drug products have been removed from previous operations. Inspection must also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection must be documented in the batch production records.
- Section 211.132(c)—Certain retail packages of OTC drug products must bear a statement that is prominently placed so consumers are alerted to the specific tamper-evident feature of the package. The labeling statement is required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing. If the tamper-evident feature chosen is one that uses an identifying characteristic, that characteristic is required to be referred to in the labeling statement.
- Section 211.132(d)—A request for an exemption from packaging and labeling requirements by a manufacturer or packer is required to be submitted in the form of a citizen petition under 21 CFR 10.30.
- Section 211.137—Requirements regarding product expiration dating and compliance with 21 CFR 201.17 are set forth.
- Section 211.160(a)—The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control

mechanisms, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanism, must be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. These requirements must be followed and documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms must be recorded and justified.

- Section 211.165(e)—The accuracy, sensitivity, specificity, and reproducibility of test methods employed by a firm must be established and documented. Such validation and documentation may be accomplished in accordance with § 211.194(a)(2).
- Section 211.166(c)—Homeopathic drug product requirements are set forth.
- Section 211.173—Animals used in testing components, in-process materials, or drug products for compliance with established specifications must be maintained and controlled in a manner that assures their suitability for their intended use. They must be identified, and adequate records must be maintained showing the history of their use.
- Section 211.180(e)—Written records required by part 211 must be maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures must be established and followed for such evaluations and must include provisions for a representative number of batches, whether approved or unapproved or rejected, and a review of complaints, recalls, returned or salvaged drug products, and investigations conducted under § 211.192 for each drug product.
- Section 211.180(f)—Procedures must be established to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations conducted under § 211.198, § 211.204, or § 211.208, any recalls, reports of inspectional observations issued, or any regulatory actions relating to good manufacturing practices brought by FDA.
- Section 211.182—Specifies requirements for equipment cleaning records and the use log.
- Section 211.184—Specifies requirements for component, drug product container, closure, and labeling records.
- Section 211. 186—Specifies master production and control records requirements.
- Section 211.188—Specifies batch production and control records requirement.
- Section 211.192—Specifies the information that must be maintained on the investigation of discrepancies found in the review of all drug product production and control records by the quality control staff.
- Section 211.194—Explains and describes laboratory records that must be retained.
- Section 211.196—Specifies the information that must be included in records on the distribution of the drug.
- Section 211.198—Specifies and describes the handling of all complaint files received by the applicant.
- Section 211.204—Specifies that records be maintained of returned and salvaged drug products and describes the procedures involved.

Written procedures, referred to here as standard operating procedures (SOPs), are required for many part 211 records. The current SOP requirements were initially provided in a final rule published in the **Federal Register** of September 29, 1978 (43 FR 45014), and are now an integral and familiar part of the drug manufacturing process. The major information collection impact of SOPs results from their creation. Thereafter, SOPs need to be periodically updated. A combined estimate for routine maintenance of SOPs is provided in table 1 of this document. The 25 SOP provisions under part 211 in the combined maintenance estimate include:

- Section 211.22(d)—Responsibilities and procedures of the quality control unit;
- Section 211.56(b)—Sanitation procedures;
- Section 211.56(c)—Use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents;
- Section 211.67(b)—Cleaning and maintenance of equipment;
- Section 211.68(a)—Proper performance of automatic, mechanical, and electronic equipment;
- Section 211.80(a)—Receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers or closures;
- Section 211.94(d)—Standards or specifications, methods of testing, and methods of cleaning, sterilizing, and processing to remove pyrogenic properties for drug product containers and closures;
- Section 211.100(a)—Production and process control;
- Section 211.110(a)—Sampling and testing of in-process materials and drug products;
- Section 211.113(a)—Prevention of objectionable microorganisms in drug products not required to be sterile;
- Section 211.113(b)—Prevention of microbiological contamination of drug products purporting to be sterile, including validation of any sterilization process;
- Section 211.115(a)—System for reprocessing batches that do not conform to standards or specifications, to insure that reprocessed batches conform with all established standards, specifications, and characteristics;
- Section 211.122(a)—Receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials;
- Section 211.125(f)—Control procedures for the issuance of labeling;
- Section 211.130—Packaging and label operations, prevention of mixup and cross contamination, identification and handling of filed drug product containers that are set aside and held in unlabeled condition, and identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch;
- Section 211.142—Warehousing;
- Section 211.150—Distribution of drug products;
- Section 211.160—Laboratory controls;
- Section 211.165(c)—Testing and release for distribution;
- Section 211.166(a)—Stability testing;
- Section 211.167—Special testing requirements;
- Section 211.180(f)—Notification of responsible officials of investigations, recalls, reports of inspectional observations, and any regulatory actions relating to good manufacturing practice;
- Section 211.198(a)—Written and oral complaint procedures, including quality control unit review of any complaint involving specifications failures, and serious and unexpected adverse drug experiences;
- Section 211.204—Holding, testing, and reprocessing of returned drug products; and
- Section 211.208—Drug product salvaging.

Although most of the CGMP provisions covered in this document were created many years ago, there will be some existing firms expanding into new manufacturing areas and startup firms that will need to create SOPs. As provided in table 1 of this document,

FDA is assuming that approximately 100 firms will have to create up to 25 SOPs for a total of 2,500 records, and the agency estimates that it will take 20 hours per recordkeeper to create 25 new SOPs, for a total of 50,000 hours.

The burden estimates for the recordkeeping requirements in table 1 of this document are based on the following factors: (1) FDA's institutional experience regarding creation and review of such procedures and similar recordkeeping requirements, and (2) data provided to FDA to prepare an economic analysis of the potential economic impact of the May 3, 1996, proposed rule entitled ''Current Good Manufacturing Practice: Proposed Amendment of Certain Requirements for Finished Pharmaceuticals'' (61 FR 20104). Annual SOP maintenance is estimated to involve 1 hour annually per SOP, totaling 25 hours annually per recordkeeper.

The May 3, 1996, proposed rule revising part 211 CGMP requirements would require additional SOPs. Cost estimates for those additional SOPs were included in the proposed rule, but are not included here. Any comments on those estimates will be evaluated in any final rule based on that proposal.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
SOP Maintenance (See list of 25 SOPs in the **SUPPLEMENTARY INFORMATION** section of this document)	4,184	1	4,184	25	104,600
New startup SOPs	100	25	2,500	20	50,000
211.34	4,184	.25	1,046	.5	523
211.67(c)	4,184	50	209,200	.25	52,300
211.68	4,184	2	8,368	1	8,368
211.68(a)	4,184	10	41,840	.5	20,920
211.68(b)	4,184	5	20,920	.25	5,230
211.72	4,184	.25	1,046	1	1,046
211.80(d)	4,184	.25	1,046	.1	105
211.100(b)	4,184	3	12,552	2	25,104
211.105(b)	4,184	.25	1,046	.25	262
211.122(c)	4,184	50	209,200	.25	52,300
211.130(e)	4,184	50	209,200	.25	52,300
211.132(c)	1,698	20	33,960	.5	16,980
211.132(d)	1,698	.2	340	.5	170
211.137	4,184	5	20,920	.5	10,460
211.160(a)	4,184	2	8,368	1	8,368
211.165(e)	4,184	1	4,184	1	4,184
211.166(c)	4,184	2	8,368	.5	4,184
211.173	1,077	1	1,077	.25	269
211.180(e)	4,184	.2	837	.25	209
211.180(f)	4,184	.2	837	1	837
211.182	4,184	2	8,368	.25	2,092
211.184	4,184	3	12,552	.5	6,276
211.186	4,184	10	41,840	2	83,680
211.188	4,184	25	104,600	2	209,200
211.192	4,184	2	8,368	1	8,368

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
211.194	4,184	25	104,600	.5	52,300
211.196	4,184	25	104,600	.25	26,150
211.198	4,184	5	20,920	1	20,920
211.204	4,184	10	41,840	.5	20,920
Total					848,625

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

Dated: March 21, 2005.

Jeffrey Shuren,

Assistant Commisssioner for Policy.

[FR Doc. 05–5976 Filed 3–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004P–0285]

Determination That ACIPHEX (Rabeprazole Sodium) Delayed-Release Tablets, 10 Milligrams, 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 ACIPHEX (rabeprazole sodium) delayed-release tablets, 10 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for rabeprazole sodium delayed-release tablets, 10 mg.

FOR FURTHER INFORMATION CONTACT: Elizabeth Sadove, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

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 typically 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 (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 (§ 314.162 (21 CFR 314.162)).

Under § 314.161(a)(1) (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.

ACIPHEX delayed-release tablets are the subject of approved NDA 20–973 held by Eisai, Inc. (Eisai). ACIPHEX (rabeprazole sodium) delayed-release tablets are a proton pump inhibitor indicated for the healing of erosive or ulcerative gastroesophageal reflux disease (GERD), maintenance of healing of erosive GERD, healing of duodenal ulcers, and treatment of pathological hypersecretory conditions, including Zollinger-Ellison Syndrome. Lachman Consultant Services, Inc., submitted a citizen petition dated July 6, 2004 (Docket No. 2004P–0285/CP1), under 21 CFR 10.30, requesting that the agency determine whether ACIPHEX delayed-release tablets, 10 mg, were withdrawn from sale for reasons of safety or effectiveness.

The agency has determined that Eisai's ACIPHEX delayed-release tablets, 10 mg, were not withdrawn from sale for reasons of safety or effectiveness. ACIPHEX delayed-release tablets, 10 mg, were approved on May 29, 2002, and Eisai has never commercially marketed the 10-mg dose. In previous instances (see the **Federal Register** of December 30, 2002 (67 FR 79640 at 79641) (addressing a relisting request for Diazepam Autoinjector)), FDA has concluded that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale. There is no indication that Eisai's decision not to market ACIPHEX delayed-release tablets, 10 mg, commercially is a function of safety or effectiveness concerns, and the petitioner has identified no data or other information suggesting that ACIPHEX delayed-release tablets, 10 mg, pose a safety risk. FDA's independent evaluation of relevant information has uncovered nothing that would indicate that this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing agency records, FDA determines that for the reasons outlined previously, ACIPHEX delayed-release tablets, 10 mg, were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list ACIPHEX (rabeprazole sodium) delayed-release tablets, 10 mg, 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 ACIPHEX delayed-