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Determination That ACIPHEX (Rabeprazole Sodium) Delayed-Release Tablets, 10 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness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(FDA) has determined that ACIPHEX (rabeprazole sodium) delayed-release tablets, 10 milligrams (mg), were not withdrawn from sale for reasons of safety or effectiveness.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-

release tablets, 10 mg, may be approved by the agency.

Dated: March 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–5975 Filed 3–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0098]

Food and Drug Administration/Drug Information Association Cross Labeling; Public Meeting; Combination Products and Mutually Conforming Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in cooperation with the Drug Information Association (DIA), is announcing a public meeting to solicit views and provide an interactive forum for discussion of stakeholders' perspectives about, and experiences with, the legal and public health issues that arise when sponsors seek to develop or market a product of one type (device, drug, or biological product) that would be labeled for use with an already approved product of a different type, and the approved product's labeling would not be changed. The input received at the meeting and comments made to the docket after the meeting will be considered in developing draft guidance on this topic.

DATES: The public meeting will be held on May 10, 2005, from 8:30 a.m. to 5 p.m. Attendees must register to attend. Submit written or electronic requests to speak at the public meeting by April 26, 2005. Submit written or electronic comments by July 8, 2005.

ADDRESSES: The public meeting will be held at the Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Rd., North Bethesda, MD. A copy of the meeting's program and registration information is available on the Internet at*http://www.diahome.org/Content/Events/05028.pdf*, by contacting the Drug Information Association, P.O. Box 827192, Philadelphia, PA 19182–7192, or 215–442–6100.

Submit written comments 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.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT:

For information about the public meeting contact: Suzanne O'Shea, Office of Combination Products, Food and Drug Administration (HFG–3), suite 200, 15800 Crabbs Branch Way, Rockville, MD 20855, 301–427–1934, FAX: 301–427–1935, e-mail: *combination@fda.gov*.

To register to speak at the public meeting contact: Amanda Carmody, Drug Information Association, P.O. Box 827192, Philadelphia, PA 19182–7192, e-mail: *Amanda.carmody@diahome.org*, or 215–442–6176.

SUPPLEMENTARY INFORMATION:

I. Background

An increasing number of combined uses for drugs and devices, drugs and biological products, or devices and biological products are being developed where the two products are independently approved, manufactured, and distributed. In some cases, when one product is already approved for a particular indication, route of administration or dose, another sponsor may develop a separate product to be used with the approved product for an indication, route of administration or dose different from the one specified in the current labeling of the approved product. Frequently, the sponsors of the two products work together to develop safety and effectiveness data and to bring the two products to market with mutually conforming labeling, i.e., labeling for each product that provides directions for using that product with the other sponsor's product. In such cases, the two products are considered a combination product under § 3.2(e)(3) (21 CFR 3.2(e)(3)), which states that a combination product includes:

> A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant changed in dose* * *.

In order for the two products to have mutually conforming labeling of the type contemplated by § 3.2(e)(3), the sponsor of the approved product ordinarily must submit a supplement to its marketing application[1] to amend the currently approved labeling to include directions for using the two products together. When sponsors work together to develop mutually conforming labeling, they usually have an ongoing relationship that enables them to resolve scientific or legal issues that may arise as a result of the two products being the responsibility of two independent sponsors. For this reason, FDA encourages sponsors to work together as much as possible when bringing to market independently developed, manufactured, and distributed products that are intended to be used together.

On occasion, however, the two sponsors do not work together, and the sponsor of a new product unilaterally develops a product intended to be used with an already approved or cleared product. The sponsor of the new product is frequently willing to develop data demonstrating the safe and effective use of both products used together. When the new product is intended to be used with the approved product in a way that is significantly different from ways described in the current labeling of the approved product (e.g., for a different indication, route of administration or dose), refusal by the sponsor of the approved product to submit a supplement[2] may preclude mutually conforming labeling. In some cases, when the two sponsors do not work together, requiring that the two products have mutually conforming labeling could prevent the development of new products. FDA is concerned that valuable products may not be developed, manufactured, or distributed because of sponsor concerns about mutually conforming labeling.

Therefore, FDA is considering whether the agency should review and approve or clear drug-device, biologic-device, or drug-biologic products, where:

- One sponsor's new product is intended for use with another sponsor's approved or cleared product;
- The approved or cleared product would be used in a way that is significantly different from the use described in its current labeling, e.g., a different indication, route of administration, or dose;
- Data are available to demonstrate the safe and effective use of the two products together;
- There is no cooperation, ongoing relationship, or right of reference between the sponsors of the two products; and
- The sponsor of the new product asks FDA to review the new product for use with the approved product under

[1] In some cases, a new 510(k) might be required.

[2] Or in some cases, a new 510(k).