no greater than 1.5 standard errors above the respective absolute and net baseline payment error rate.

The QIOs will also be judged in terms of timeliness of reviews. Monitoring activities must be summarized for payment error rates and hospital admission, coding, and billing patterns for short-term acute care inpatient FFS reimbursements in the QIO's State/jurisdiction including hospital profiling and trend monitoring. The QIO must submit its summary electronically to the Project Officer via a designated database as directed by CMS. Whether demonstrations of reductions in dollars or percent dollars paid in error and whether substantive knowledge are gained in the project will be determined by the Task 3b GTL and the QIO's Project Officer.

Task 4: Special Studies and Projects

A Special Project is defined as work that we direct a QIO to perform or work that a QIO elects to perform with our approval that is not defined under Tasks 1–3 of the contract. The Special Project work must fall within the scope of the contract and of section 1154 of the Act. The Special Project must be conducted in accordance with contract sections B.4, Task 4 Special Projects; G.18, Procedures for Special Projects; and H.12, CMS-Directed Subcontracts/Special Project Lead QIOs. The term ''Special Project'' is a more accurate term for the type of activities and requirements characteristically implemented under Task 4. Other terms, previously commonly used, for activities under this task include ''special study'', ''special study project'', and ''special work.''

All Special Projects awarded/approved under Task 4 will be evaluated individually. The QIO's success or failure on a Special Project will not be factored into the evaluation of the QIO's work under Tasks 1–3 of the contract, except for projects funded to meet the requirements of Task 3b: Hospital Payment Monitoring Program. The assessment of performance on all other special projects under Task 4 will affect the QIO's eligibility to receive funding for additional special projects under the current or subsequent QIO contracts, but will not affect eligibility for non-competitive renewal of the QIO contract. Although individual projects may include additional project-specific assessment criteria and performance measures, every project awarded/approved under Task 4 is subject to evaluation on at least the following dimensions of performance, which apply to any and all projects awarded/approved under Task 4:

- Completion of specific tasks (deliverables) required in the special project.
- Financials.
- Appropriateness of QIO staffing for this special project including number of staff as well as skill sets of staff.
- Performance in meeting the needs of QIOs, other Quality Improvement Organization Support Centers, GTLs, etc., and the quality of activities to improve performance.
- Participation in other improvement activities.
- Efforts to address issues/barriers identified.

Performance assessment for each project will be conducted jointly by the QIO's regularly assigned CMS Project Officer and the specific Special Project GTL (SPGTL).

Authority: Section 1153 of the Social Security Act (42 U.S.C. 1320c–2) (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: March 8, 2007.

Leslie Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Editorial Note: The Office of the Federal Register received this document on August 2, 2007.

[FR Doc. E7–15342 Filed 8–6–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Privacy Act of 1974; Report of a New System of Records

AGENCY: Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS).

ACTION: Notice of a New System of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, we are proposing to establish a new system titled, ''Healthcare Common Procedure Coding System (HCPCS) Level II, System No. 09–70–0576.'' In October 2003, the Secretary of HHS delegated authority under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to CMS to maintain and distribute HCPCS Level II Codes. Level II of the HCPCS is a standardized coding system that is used primarily to identify products and services not included in the HCPCS Level I Current Procedural Terminology (CPT) codes, such as: Injectable drugs administered in a physician office; durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office; and ambulance services. HCPCS Level II codes were established to identify these products on insurance claims. There are about 4000 HCPCS Level II codes available for assignment by insurers in accordance with their policies.

The primary purpose of this system is to facilitate the management and maintenance of the HCPCS Level II code set. Information in this system will also be used to: (1) Support regulatory and policy functions performed within the Agency or by a contractor, consultant, or grantee; (2) assist another Federal or state agency; (3) support litigation involving the Agency related to this system; and (4) combat fraud, waste, and abuse in certain health benefits programs. We have provided background information about the proposed system in the **SUPPLEMENTARY INFORMATION** section below. Although the Privacy Act requires only that the ''routine use'' portion of the system be published for comment, CMS invites comments on all portions of this notice. See *Effective Dates* section for comment period.

DATES: *Effective Dates:* CMS filed a new SOR report with the Chair of the House Committee on Oversight and Government Reform, the Chair of the Senate Committee on Homeland Security & Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on August 1, 2007. To ensure that all parties have adequate time in which to comment, the new system will become effective 30 days from the publication of the notice, or 40 days from the date it was submitted to OMB and the Congress, whichever is later. We may defer implementation of this system or one or more of the routine use statements listed below if we receive comments that persuade us to defer implementation.

ADDRESSES: The public should address comments to: CMS Privacy Officer, Division of Privacy Compliance, Enterprise Architecture and Strategy Group, CMS, Mail Stop N2–04–27, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.–3 p.m., eastern daylight time.

FOR FURTHER INFORMATION CONTACT: Trish Brooks, Division of Home Health, Hospice, and HCPCS, Chronic Care

Policy Group, Center for Medicare Management, CMS, Mail Stop C5–09–16, 7500 Security Boulevard, Baltimore, Maryland 21244–1850. Her telephone number is 410–786–4561, or email at *Trish.Brooks@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION: Each year, in the United States, health care insurers process over 5 billion claims for payment. For Medicare and other health insurance programs to ensure that these claims are processed in an orderly and consistent manner, standardized coding systems are essential. The HCPCS Level II Code Set is one of the standard code sets adopted under the HIPAA, used for this purpose.

The HCPCS Level II coding system is a comprehensive and standardized system that classifies similar products that are medical in nature into categories for the purpose of efficient claims processing. For each alphanumeric HCPCS code, there is descriptive terminology that identifies a category of like items. These codes are used primarily for billing purposes. For example, suppliers use HCPCS Level II codes to identify items on claim forms that are being billed to a private or public health insurer.

HCPCS is a system for identifying items and services. While these codes are used for billing purposes, decisions regarding the addition, deletion, or revision of HCPCS codes are made independent of the process for making determinations regarding coverage and payment. Currently, there are national HCPCS codes representing approximately 4,000 separate categories of like items or services that encompass millions of products from different manufacturers. When submitting claims, suppliers are required to use one of these codes to identify the items they are billing. The descriptor that is assigned to a code represents a category of similar items.

Anyone can submit a request for modifications to the HCPCS Level II National Code Set and/or provide comments regarding pending requests. The HCPCS coding review process is an ongoing continuous process; requests and other correspondence may be submitted at any time throughout the year. However, for a consideration of coding action with an effective date of January 1, a completed application must be received by January 3rd, or the first business day of the year prior. Applications received after January 3rd will be considered in the subsequent cycle.

I. Description of the Proposed System of Records

A. Statutory and Regulatory Basis for the System

Authority for this system is given under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104–191, its implementing regulation on ''Code Sets'' (45 Code of Federal Regulations Part 162, Subpart J) and 65 **Federal Register** 50312 (8–17–00).

B. Collection and Maintenance of Data in the System

Information is collected for this system on individuals who voluntarily submit information regarding any modification and/or applications to modify the HCPCS Level II Code Set. Information collected for this system will include, but is not limited to, applicant name, company name, product's generic or trade name, company mailing address, email address, telephone number, and fax number.

II. Agency Policies, Procedures, and Restrictions on the Routine Use

A. Agency Policies, Procedures, and Restrictions on the Routine Use

The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a ''routine use.'' The government will only release HCPCS information that can be associated with an individual as provided for under ''Section III. Proposed Routine Use Disclosures of Data in the System.'' Both identifiable and non-identifiable data may be disclosed under a routine use.

We will only collect the minimum personal data necessary to achieve the purpose of management of HCPCS. CMS has the following policies and procedures concerning disclosures of information that will be maintained in the system. Disclosure of information from the system will be approved only to the extent necessary to accomplish the purpose of the disclosure and only after CMS:

1. Determines that the use or disclosure is consistent with the reason that the data is being collected, e.g., to facilitate the management and maintenance of the HCPCS Level II code set.

2. Determines that:

a. The purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

b. The purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and

c. There is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

3. Requires the information recipient to:

a. Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

b. Remove or destroy at the earliest time all patient-identifiable information; and

c. Agree to not use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

4. Determines that the data are valid and reliable.

III. Proposed Routine Use Disclosures of Data in the System

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To Agency contractors, consultants, or grantees who have been contracted by the Agency to assist in accomplishment of a CMS function relating to the purposes for this system and who need to have access to the records in order to assist CMS.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual or similar agreement with a third party to assist in accomplishing CMS functions relating to purposes for this system.

CMS occasionally contracts out certain of its functions when this would contribute to effective and efficient operations. CMS must be able to give a contractor, consultant, or grantee whatever information is necessary for the contractor to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor, consultant, or grantee from using or disclosing the information for any purpose other than that described in the contract and to return or destroy all information at the completion of the contract.

2. To another Federal or state agency to:

a. Contribute to the accuracy of CMS's proper payment of Medicare benefits,

b. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds, and/or

c. Assist Federal/state Medicaid programs within the state.

Other Federal or state agencies in their administration of a Federal health program may require HCPCS information in order to ensure that claims are processed in an orderly and consistent manner.

3. To the Department of Justice (DOJ), court or adjudicatory body when

a. The Agency or any component thereof; or

b. Any employee of the Agency in his or her official capacity; or

c. Any employee of the Agency in his or her individual capacity where the DOJ has agreed to represent the employee; or

d. The United States Government; is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation.

Whenever CMS is involved in litigation, or occasionally when another party is involved in litigation and CMS's policies or operations could be affected by the outcome of the litigation, CMS would be able to disclose information to the DOJ, court or adjudicatory body involved. A determination would be made in each instance that, under the circumstances involved, the purposes served by the use of the information in the particular litigation is compatible with a purpose for which CMS collects the information.

4. To a CMS contractor (including, but not necessarily limited to Medicare administrative contractors, fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such program.

We contemplate disclosing information under this routine use only in situations in which CMS may enter into a contractual relationship or grant with a third party to assist in accomplishing CMS functions relating to the purpose of combating fraud, waste, and abuse.

CMS occasionally contracts out certain of its functions and makes grants when doing so would contribute to effective and efficient operations. CMS must be able to give a contractor or grantee whatever information is necessary for the contractor or grantee to fulfill its duties. In these situations, safeguards are provided in the contract prohibiting the contractor or grantee from using or disclosing the information for any purpose other than that described in the contract and requiring the contractor or grantee to return or destroy all information.

5. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste, or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such programs.

Other agencies may require HCPCS information for the purpose of combating fraud, waste and abuse in such Federally-funded programs.

B. Additional Provisions Affecting Routine Use Disclosures

To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, Subparts A and E) 65 FR 82462 (12–28–00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.'' (See 45 CFR 164.512(a)(1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the specified population is so small that an individual could, because of the small size, use this information to deduce the identity of the applicant).

IV. Safeguards

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, the Federal Records Act of 1950, as amended, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook, CMS Information Security Handbook, and the National Archives and Records Administration's General Record Schedules and CMS' Records Schedules.

V. Effects of the Proposed System of Records on Individual Rights

CMS proposes to establish this system in accordance with the principles and requirements of the Privacy Act and will collect, use, and disseminate information only as prescribed therein. Data in this system will be subject to the authorized releases in accordance with the routine uses identified in this system of records.

CMS will take precautionary measures to minimize the risks of unauthorized access to the records and the potential harm to individual privacy or other personal or property rights of applicants whose data are maintained in the system. CMS will collect only that information necessary to perform the system's functions. In addition, CMS will make disclosure from the proposed system only with consent of the subject

individual, or his/her legal representative, or in accordance with an applicable exception provision of the Privacy Act. CMS, therefore, does not anticipate an unfavorable effect on individual privacy as a result of the disclosure of information relating to individuals.

Date: July 30, 2007.

Charlene Frizzera,

Chief Operating Officer, Centers for Medicare & Medicaid Services.

SYSTEM NO.: 09–70–0576.

SYSTEM NAME:

''Healthcare Common Procedure Coding System (HCPCS) Level II''.

SECURITY CLASSIFICATION:

Level 3 Privacy Act Sensitive.

SYSTEM LOCATION:

Centers for Medicare & Medicaid Services (CMS), 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Information is collected for this system on individuals who voluntarily submit information regarding any modification and/or applications to modify the HCPCS Level II Code Set.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information collected for this system will include, but is not limited to, applicant name, company name, product's generic or trade name, company mailing address, e-mail address, telephone number, and fax number.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for this system is given under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104–191, its implementing regulation on ''Code Sets'' (45 Code of Federal Regulations part 162, Subpart J) and 65 **Federal Register** 50312 (8–17–00).

PURPOSE (S) OF THE SYSTEM:

The primary purpose of this system is to facilitate the management and maintenance of the HCPCS Level II code set. Information in this system will also be used to: (1) Support regulatory and policy functions performed within the Agency or by a contractor, consultant, or grantee; (2) assist another Federal or state agency; (3) support litigation involving the Agency related to this system; and (4) combat fraud, waste, and abuse in certain health benefits programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OR USERS AND THE PURPOSES OF SUCH USES:

A. The Privacy Act allows us to disclose information without an individual's consent if the information is to be used for a purpose that is compatible with the purpose(s) for which the information was collected. Any such compatible use of data is known as a ''routine use.'' The proposed routine uses in this system meet the compatibility requirement of the Privacy Act. We are proposing to establish the following routine use disclosures of information maintained in the system:

1. To Agency contractor, consultant, or grantee who have been contracted by the Agency to assist in accomplishment of a CMS function relating to the purposes for this system and who need to have access to the records in order to assist CMS.

2. To another Federal or state agency to:

a. Contribute to the accuracy of CMS's proper payment of Medicare benefits,

b. Enable such agency to administer a Federal health benefits program, or as necessary to enable such agency to fulfill a requirement of a Federal statute or regulation that implements a health benefits program funded in whole or in part with Federal funds, and/or

c. Assist Federal/state Medicaid programs within the state.

3. To the Department of Justice (DOJ), court or adjudicatory body when

a. The Agency or any component thereof; or

b. Any employee of the Agency in his or her official capacity; or

c. Any employee of the Agency in his or her individual capacity where the DOJ has agreed to represent the employee; or

d. The United States Government; is a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation.

4. To a CMS contractor (including, but not necessarily limited to Medicare administrative contractors, fiscal intermediaries and carriers) that assists in the administration of a CMS-administered health benefits program, or to a grantee of a CMS-administered grant program, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such program.

5. To another Federal agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States (including any State or local governmental agency), that administers, or that has the authority to investigate potential fraud, waste, or abuse in, a health benefits program funded in whole or in part by Federal funds, when disclosure is deemed reasonably necessary by CMS to prevent, deter, discover, detect, investigate, examine, prosecute, sue with respect to, defend against, correct, remedy, or otherwise combat fraud, waste, or abuse in such programs.

B. Additional Provisions Affecting Routine Use Disclosures

To the extent this system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, Subparts A and E) 65 FR 82462 (12–28–00). Disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.'' (See 45 CFR 164.512(a)(1)).

In addition, our policy will be to prohibit release even of data not directly identifiable, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the specified population is so small that an individual could, because of the small size, use this information to deduce the identity of the applicant).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

All records are stored on electronic and hard copy media.

RETRIEVABILITY:

Information can be retrieved by applicant name, e-mail address, manufacturer name, product name, generic name, or code assigned.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational

and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations may apply but are not limited to: The Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, the Federal Records Act of 1950, as amended, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: All pertinent National Institute of Standards and Technology publications; the HHS Information Systems Program Handbook, CMS Information Security Handbook, and the National Archives and Records Administration's General Record Schedules and CMS' Records Schedules.

RETENTION AND DISPOSAL:

CMS will retain information for a total period of 15 years. All claims-related records are encompassed by the document preservation order and will be retained until notification is received from DOJ.

SYSTEM MANAGER AND ADDRESS:

Director, Chronic Care Policy Group, Centers for Medicare Management, CMS, Mail Stop C5–09–16, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, and for verification purposes, the subject individual's name (woman's maiden name, if applicable).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5(a)(2).)

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

Sources of information contained in this records system include data collected from HCPCS applications, submitted by the individuals who voluntarily apply for HCPCS Level II Code modifications.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. E7–15250 Filed 8–6–07; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006P–0462]

Determination That PREVACID NAPRAPAC (Copackaged Lansoprazole Delayed-Release 15–Milligram Capsules and Naproxen 250–Milligram Tablets) 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) has determined that PREVACID NAPRAPAC 250 (copackaged lansoprazole delayed-release 15-milligram (mg) capsules and naproxen 250-mg tablets) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for copackaged lansoprazole delayed-release 15-mg capsules and naproxen 250-mg tablets.

FOR FURTHER INFORMATION CONTACT: Marguerita B. Sims, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5041.

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 an 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 (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.

PREVACID NAPRAPAC 250 is the subject of NDA 21–507 held by Tap Pharmaceuticals, Inc. (TAP). PREVACID NAPRAPAC 250 is a copackaged drug product that contains Prevacid (lansoperazole) 15-mg delayed-release capsules (a proton-pump inhibitor) and Naprosyn (naproxen) 250-mg tablets (a nonsteroidal anti-inflammatory drug product (NSAID) with analgesic and antipyretic properties). PREVACID NAPRAPAC 250 is indicated for reducing the risk of NSAID-associated gastric ulcers in patients with a history of documented gastric ulcer(s) who require the use of an NSAID for treatment of the signs and symptoms of rheumatoid arthritis, osteoarthritis, and/or ankylosing spondylitis. TAP's PREVACID NAPRAPAC 250 was discontinued in October 2006.

In a citizen petition received on November 13, 2006 (Docket No. 2006P–0462/CP1), submitted under 21 CFR 10.30 and in accordance with § 314.161, Robert W. Pollock of Lachman