- Systems security.
- ADP maintenance (configuration management, testing, change management, and security).
- Disaster recovery plan/systems contingency plan.
- Data and reporting requirements implementation.
- Internal controls establishment and use, including the degree to which the contractor cooperates with the Secretary in complying with the FMFIA.
- Implementation of the Electronic Data Interchange (EDI) standards adopted for use under the HIPAA.
- Implementation of our general instructions.

VII. Action Based on Performance Evaluations

[If you choose to comment on this section, please include the caption ''Action Based on Performance Evaluations'' at the beginning of your comments.]

We evaluate a contractor's performance against applicable program requirements for each criterion. Each contractor must certify that all information submitted to us relating to the contract management process, including, without limitation, all files, records, documents and data, whether in written, electronic, or other form, is accurate and complete to the best of the contractor's knowledge and belief. A contractor is required to certify that its files, records, documents, and data are not manipulated or falsified in an effort to receive a more favorable performance evaluation. A contractor must further certify that, to the best of its knowledge and belief, the contractor has submitted, without withholding any relevant information, all information required to be submitted for the contract management process under the authority of applicable law(s), regulation(s), contract(s), or our manual provision(s). Any contractor that makes a false, fictitious, or fraudulent certification may be subject to criminal or civil prosecution, as well as appropriate administrative action. This administrative action may include debarment or suspension of the contractor, as well as the termination or nonrenewal of a contract.

If a contractor meets the level of performance required by operational instructions, it meets the requirements of that criterion. When we determine a contractor is not meeting performance requirements, we will use the terms ''major nonconformance'' or ''minor nonconformance'' to classify our findings. A major nonconformance is a nonconformance that is likely to result in failure of the supplies or services, or to materially reduce the usability of the supplies or services for their intended purpose. A minor nonconformance is a nonconformance that is not likely to materially reduce the usability of the supplies or services for their intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the supplies or services. The contractor will be required to develop and implement PIPs for findings determined to be either a major or minor nonconformance. The contractor will be monitored to ensure effective and efficient compliance with the PIP, and to ensure improved performance when requirements are not met.

The results of performance evaluations and assessments under all criteria applying to FIs, carriers, and RHHIs will be used for contract management activities and will be published in the contractor's annual Report of Contractor Performance (RCP). We may initiate administrative actions as a result of the evaluation of contractor performance based on these performance criteria. Under sections 1816 and 1842 of the Act, we consider the results of the evaluation in our determinations when—

- Entering into, renewing, or terminating agreements or contracts with contractors; and
- Deciding other contract actions for intermediaries and carriers (such as deletion of an automatic renewal clause). These decisions are made on a case-by-case basis and depend primarily on the nature and degree of performance. More specifically, these decisions depend on the following:

+ Relative overall performance compared to other contractors.
+ Number of criteria in which nonconformance occurs.
+ Extent of each nonconformance.
+ Relative significance of the requirement for which nonconformance occurs within the overall evaluation program.
+ Efforts to improve program quality, service, and efficiency.
+ Deciding the assignment or reassignment of providers and designation of regional or national intermediaries for classes of providers.

We make individual contract action decisions after considering these factors in terms of their relative significance and impact on the effective and efficient administration of the Medicare program.

In addition, if the cost incurred by the FIs, RHHI, or carrier to meet its contractual requirements exceeds the amount that we find to be reasonable and adequate to meet the cost that must be incurred by an efficiently and economically operated FIs or carrier, these high costs may also be grounds for adverse action.

VIII. Collection of Information Requirements

This document does not impose information collection and record keeping requirements. Consequently the Office of Management and Budget need not review it under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IX. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are unable to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the ''Comment Date'' section of this notice, and, if we proceed with a subsequent document, we will respond to the comments in the section entitled as ''Analysis of and Response to Public Comments Received on FY 2008 Criteria and Standards'' of that document.

Authority: Sections 1816(f), 1834(a)(12), and 1842(b) of the Social Security Act (42 U.S.C. 1395h(f), 1395m(a)(12), and 1395u(b)).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 24, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Editorial Note: This document was received at the Office of the Federal Register on September 26, 2007.

[FR Doc. 07–4826 Filed 9–28–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0353]

Drug Products Containing Hydrocodone; Enforcement Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to take enforcement action, as described in this notice, against

unapproved drug products containing hydrocodone bitartrate, or any other salt or ester of hydrocodone (hereinafter collectively ''hydrocodone''), and persons who manufacture or cause the manufacture of such products or their shipment in interstate commerce. Unapproved hydrocodone products have been implicated in reports of medication errors, including improper dosing and dispensing the wrong drug. Some of these products omit important labeling warnings and information or are inappropriately labeled for use in young children. Drug products containing hydrocodone are new drugs that require approved applications because they are not generally recognized as safe and effective. Manufacturers who wish to market a drug product containing hydrocodone must obtain FDA approval of a new drug application (NDA) or an abbreviated new drug application (ANDA).

DATES: This notice is effective October 1, 2007.

Subject to the limitations set forth in section II.B of this notice, for marketed unapproved drug products containing hydrocodone that have a National Drug Code (NDC) number listed with FDA under section 510 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360) on the effective date of this notice (''currently marketed and listed hydrocodone products''), the agency intends to exercise its enforcement discretion after October 1, 2007 as follows. FDA does not intend to initiate action to enforce section 505(a) of the act (21 U.S.C. 355(a)) (''drug enforcement actions'') against a person[1] based solely on the person manufacturing, or otherwise introducing or delivering for introduction into interstate commerce (''shipping''), currently marketed and listed hydrocodone products, unless such a person is still manufacturing or shipping such products on or after October 31, 2007 with a label or labeling that, as of October 1, 2007, indicates any use for children under 6 years of age. FDA does not intend to initiate drug enforcement actions based solely on a person manufacturing currently marketed and listed hydrocodone products that are not labeled for use in children under 6 years of age unless such person is still manufacturing them on or after December 31, 2007. Further, FDA does not intend to initiate drug enforcement actions based solely on a person shipping currently marketed and listed hydrocodone products that are not labeled for use in children under 6 years of age unless such person is still shipping them on or after March 31, 2008. Unapproved drug products containing hydrocodone that are not currently marketed, or that are currently marketed but are not listed with the agency on the effective date of this notice, must, as of the effective date of this notice, have approved applications prior to the drug products' introduction or delivery for introduction into interstate commerce. Submission of an application does not excuse timely compliance with this notice.

ADDRESSES: All communications in response to this notice should be identified with Docket No. 2007N–0353 and directed to the appropriate office listed as follows:

Regarding applications under section 505(b) of the act: Division of Analgesics, Anesthetics, and Rheumatology Products (for analgesic formulations/indications), or Division of Pulmonary and Allergy products (for antitussive formulations/indications), Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993–0002.

Regarding applications under section 505(j) of the act: Office of Generic Drugs, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

All other communications: Jennifer Devine, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Jennifer Devine, Center for Drug Evaluation and Research (HFD–310), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–8965, e-mail: *jennifer.devine@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Drug Efficacy Study Implementation (DESI) Review

When initially enacted in 1938, the act required that ''new drugs'' be approved for safety by FDA before they could legally be sold in interstate commerce. To this end, the act made it the sponsor's burden to show FDA that its drug was safe through the submission of an NDA. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were identical, related, or similar (IRS)[2] to the approved drug to be ''covered'' by that approval, and allowed those IRS drugs to be marketed without independent approval.

In 1962, Congress amended the act to require that new drugs be proven effective for their labeled indications, as well as safe. This amendment also required FDA to conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962. FDA contracted with the National Academy of Science/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of more than 3,400 products that were approved only for safety. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The agency reviewed and reevaluated the reports and published its findings in **Federal Register** notices. DESI was FDA's administrative implementation of the NAS/NRC reports. DESI covered the 3,400 products specifically reviewed by NAS/NRC, as well as the even larger number of IRS products that entered the market without FDA approval.

All drugs covered in the DESI review are ''new drugs'' under the act. If FDA's final DESI determination classifies a drug product as ineffective, that drug product and those IRS to it can no longer be marketed and are subject to enforcement action as unapproved new drugs. If FDA's final DESI determination classifies the drug product as effective for its labeled indications, the drug can be marketed provided it is the subject of an application approved for safety and efficacy. Those drug products with NDAs approved before 1962 for safety therefore require approved supplements to their original applications; IRS drug products require an approved NDA or ANDA, as appropriate. Furthermore, labeling for drug products classified as effective may contain only those indications for which the review found the product effective unless the firm marketing the product has received an approval for the additional indication(s).

B. DESI Review of Hydrocodone Products

FDA first approved hydrocodone for use as an antitussive in the United States on March 23, 1943 (NDA 5–213,

[1] A ''person'' includes individuals, partnerships, corporations, or associations (21 U.S.C. 321(e)).

[2] Section 310.6(b)(1) (21 CFR 310.6(b)(1)) provides: ''An identical, related, or similar drug includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety as well as of any drug moiety related in chemical structure of known pharmacological properties.''

HYCODAN, submitted by ENDO Laboratories, Inc.). A subtherapeutic amount of homatropine methylbromide was later added to this product to help prevent abuse or intentional overdose. Two different hydrocodone products (including HYCODAN) were reviewed under the DESI program. In March 1982, FDA determined that the application holder of NDA 6–529, CODITRATE SYRUP containing hydrocodone bitartrate and potassium guaiacolsulfonate, held by The Central Pharmaceutical Co., failed to demonstrate that each component made a contribution to the claimed effect of the CODITRATE SYRUP (47 FR 11973, March 19, 1982). In May 1982, FDA withdrew approval of NDA 6–529 based on lack of substantial evidence of effectiveness (47 FR 21301, May 18, 1982). In June 1982, FDA classified HYCODAN syrup, tablets, and powder containing hydrocodone bitartrate and homatropine methylbromide (NDA 5–213) as effective for symptomatic relief of cough, and further classified the product as a new drug for which an approved NDA was required prior to marketing (47 FR 23809, June 1, 1982). As described in § 310.6, agency determinations regarding new drug status set forth in these notices also apply to any drug products that are IRS to the drugs named in the DESI notices. Currently marketed analgesic formulations were first marketed after the 1962 amendments to the act, and thus were not reviewed under the DESI program.

C. Hydrocodone Products

Hydrocodone is an opioid derived from codeine and is recognized for both analgesic and antitussive effects. FDA has approved applications for prescription hydrocodone drug products intended to treat pain and for prescription hydrocodone products intended to suppress cough. Hydrocodone (bulk or single entity product) is a Schedule II narcotic under the Controlled Substances Act (21 U.S.C. 801 *et seq.*), and combination products with hydrocodone and non-narcotic active ingredients, which are labeled either for use as analgesics or for use as antitussives, are Schedule III. Hydrocodone is one of the most potent drugs available to relieve pain and treat cough symptoms. Despite its medical benefit for such purposes, however, hydrocodone is also a potentially lethal drug of abuse. Overdose can produce respiratory depression, coma, and cardiac arrest, in addition to other adverse events. Hydrocodone use can also impair physical or mental capabilities needed to drive, operate machinery, or perform other potentially hazardous activities. It can also lead to psychological and physical drug dependence. Analysis of population-based epidemiologic data from the Substance Abuse and Mental Health Services Administration National Survey on Drug Use and Health shows that the misuse and abuse associated with the opioid class overall has been increasing in recent years. For example, in 2005, more than 17 million Americans aged 12 or older reported non-medical use of a hydrocodone pain reliever at least once in their lifetime, representing eight percent of the population aged 12 years or older. Of those 17 million individuals, more than 8 million reported using hydrocodone in the past year.

As of 2005,[3] FDA has received more than 400 spontaneous reports[4] of serious adverse events associated with all antitussive hydrocodone-containing products. While significant under-reporting of adverse events from spontaneous sources in the general population occurs, the adverse event categories most often reported in association with such hydrocodone-containing products involve: (1) The central nervous system, including psychotic behavior and drug abuse; (2) the gastrointestinal tract, including nausea, vomiting, and constipation; (3) the cardiopulmonary system, including cardiac arrest and respiratory depression; (4) hypersensitivity, including pruritis, dermatitis, and pharyngeal edema; and (5) intentional and unintentional overdose.

While many of the types of adverse events associated with approved and unapproved products are generally similar, there are additional risks associated with the unapproved products. For instance, the agency has received reports of medication errors associated with formulation changes, such as changing the strength of the active ingredient, and reports of confusion based on similarity between the proprietary names of unapproved hydrocodone-containing antitussive products and other drug products. Look-alike and sound-alike similarities between the product names may have contributed to reported medication errors. FDA reviews and approves proposed proprietary names as part of the drug approval process, thereby helping to minimize potential safety issues that could be associated with product name confusion. In addition, changes in the formulation of unapproved products may cause healthcare practitioners to inadvertently prescribe the wrong dose or combination of active ingredients. The drug approval requirement allows the agency to evaluate proposed changes to approved product formulations to ensure that such modifications meet FDA standards for safety and efficacy, and can also help ensure that formulation changes are accompanied by any appropriate changes in product trade names or labeling, or other measures that may be warranted to minimize confusion and risks to patients. Modifications of product formulation that skirt FDA's drug approval process thus pose an increased risk of confusing healthcare practitioners and causing harm to consumers, such as under- or overdose, particularly in pediatric patients.

Variations and omissions in labeling information for unapproved hydrocodone-containing antitussive drug products also pose significant safety concerns. For example, labeling for approved antitussive products explains that the safety and effectiveness of such products in pediatric patients under 6 years old have not been established, and does not indicate any approved dosage for that population. By contrast, there is unapproved drug product labeling that, for example, states that children as young as 2 years old may use the product ''as directed by a physician,'' or that includes dosage instructions purported to be appropriate for children as young as 2 years old. Moreover, some unapproved product labeling omits or changes safety warnings or other information that is important to ensure safe use, such as drug interactions or potential adverse experiences.

Finally, even the expected risks associated with use of approved products that contain hydrocodone are potentially greater for unapproved products because the quality, safety, and efficacy of unapproved formulations have not been demonstrated to FDA. For example, the ingredients and bioavailability of unapproved products have not been submitted for FDA review, nor has FDA had the opportunity to assess the adequacy of their chemistry, manufacturing, and controls specifications.

[3]Data in the current system dates back to 1969, when FDA first implemented an adverse event reporting system.

[4]A ''spontaneous report'' is a report from an individual (e.g., a healthcare professional or consumer) to a sponsor or FDA that describes a suspected adverse event.

II. Legal Status

A. Hydrocodone Products Are New Drugs Requiring Approved Applications

Under its DESI review, FDA determined that hydrocodone bitartrate is a new drug. Firms must, therefore, have an approved application before marketing any drug product that contains hydrocodone bitartrate, or any other salt or ester of hydrocodone (collectively, ''hydrocodone''). There are numerous approved formulations available for both analgesic and antitussive indications. There are many approved applications for hydrocodone-containing analgesic products, generally in combination with acetaminophen, ibuprofen, or, less commonly, aspirin. It appears that all currently marketed analgesic formulations that have an NDC number listed with the agency are approved. There are several approved antitussive formulations, including HYCODAN syrup and tablets, and their approved generic equivalents. There is also an approved application for a hydrocodone polistirex and chlorpheniramine polistirex combination suspension, extended-release product (NDA 19–111), marketed as TUSSIONEX. However, there are hundreds of unapproved hydrocodone-containing products marketed as antitussives that are listed with FDA. Such products include, but are not limited to, combinations with an expectorant, such as guaifenesin, or a decongestant, such as phenylephrine or pseudoephedrine.

B. Notice of Enforcement Action

Although not required to do so by the Administrative Procedure Act (5 U.S.C. Subchapter II), the act, or any rules issued under its authority, or for any other legal reason, FDA is providing this notice to persons who are marketing unapproved products containing hydrocodone that the agency intends to take enforcement action against such products and those who manufacture them or cause them to be manufactured or shipped in interstate commerce. Consistent with the priorities identified in the agency's guidance entitled ''Marketed Unapproved Drugs—Compliance Policy Guide'' (the Marketed Unapproved Drugs CPG), the agency is taking action at this time against these products because: (1) As described in section I of this document, hydrocodone is a drug with significant safety risks and (2) there are FDA-approved drug products containing hydrocodone; thus the continued marketing of unapproved versions is a direct challenge to the drug approval process.

Manufacturing or shipping unapproved products containing hydrocodone can result in enforcement action, including seizure, injunction, or other judicial or administrative proceeding. Consistent with policies described in the Marketed Unapproved Drugs CPG, the agency does not expect to issue a warning letter or any other further warning to firms marketing unapproved drug products containing hydrocodone prior to taking enforcement action. The agency also reminds firms that, as stated in the Marketed Unapproved Drugs CPG, any unapproved drug marketed without a required approved drug application is subject to agency enforcement action at any time. The issuance of this notice does not in any way obligate the agency to issue similar notices or any notice in the future regarding marketed unapproved drugs.[5]

As described in the Marketed Unapproved Drugs CPG, the agency may, at its discretion, exercise its enforcement discretion and identify a period of time during which the agency does not intend to initiate an enforcement action against a currently marketed unapproved drug on the ground that it lacks an approved application under section 505 of the act in order to, for example, preserve access to medically necessary drugs or ease disruption to affected parties. With respect to unapproved hydrocodone drug products, the agency intends to exercise its enforcement discretion for only a limited period of time because: (1) The lack of uniformity in the labeling of unapproved drug products poses serious safety risks (particularly for unapproved products inappropriately labeled for use in young children); (2) there are numerous approved products, including ones containing hydrocodone, that may be used to treat the symptoms of cough in most instances; and (3) there are numerous approved hydrocodone analgesic formulations on the market. Therefore, the agency intends to implement this notice as follows.

This notice is effective October 1, 2007. However, for unapproved drug products containing hydrocodone that are currently marketed and listed (i.e., that have an NDC number listed with FDA on the date of this notice), the agency intends to exercise its enforcement discretion as follows. FDA does not intend to initiate action to enforce section 505(a) of the act (''drug enforcement actions''), against a person based solely on the person manufacturing or otherwise introducing, or delivering for introduction into interstate commerce (''shipping''), such products unless such a person is still manufacturing or shipping such products on or after October 31, 2007 with a label or labeling that, as of October 1, 2007 indicates any use for children under 6 years of age. FDA does not intend to initiate drug enforcement actions based solely on a person manufacturing currently marketed and listed unapproved hydrocodone products that are not labeled for use in children under 6 years of age unless the person is still manufacturing them on or after December 31, 2007. FDA does not intend to initiate drug enforcement actions based solely on a person shipping currently marketed and listed unapproved hydrocodone drug products that are not labeled for use in children under 6 years of age unless a person is still shipping them on or after March 31, 2008.[6]

The agency, however, does not intend to exercise its enforcement discretion as outlined previously if: (1) A person manufacturing or shipping an unapproved product covered by this notice is violating other provisions of the act or (2) it appears that a person, in response to this notice, increases the manufacture or interstate shipment of unapproved drug products covered by this notice above the person's usual volume during these periods. Nothing in this notice, including FDA's intent to exercise its enforcement discretion, alters any person's liability or obligations in any other enforcement action, or precludes the agency from initiating or proceeding with enforcement action in connection with any other alleged violation of the act, whether or not related to an unapproved drug product covered by this notice. Similarly, a person who is or becomes enjoined from marketing unapproved drugs may not resume marketing

[5]The agency's general approach in dealing with these products in an orderly manner is spelled out in the Marketed Unapproved Drugs CPG. That CPG, however, provides notice that any product that is being marketed illegally, and the persons responsible for causing the illegal marketing of the product, are subject to FDA enforcement action at any time.

[6]If FDA finds it necessary to take enforcement action against a product covered by this notice, the agency may take action relating to all of the defendant's other violations of the act at the same time. For example, if a firm continues to manufacture or market a product covered by this notice after the applicable enforcement date has passed, to preserve limited agency resources, FDA may take enforcement action relating to all of the firm's unapproved drugs that require applications at the same time (see, e.g., *United States* v. *Sage Pharmaceuticals*, 210 F.3d 475, 479-480 (5th Cir. 2000) (permitting the agency to combine all violations of the act in one proceeding, rather than taking action against multiple violations of the act in ''piecemeal fashion'')).

unapproved hydrocodone products based on FDA's exercise of enforcement discretion as set forth in this notice. FDA also will not exercise its enforcement discretion with respect to continued manufacturing or shipping of any combination drug product that contains a drug subject to an earlier deadline for the exercise of agency enforcement discretion.[7]

Drug manufacturers and distributors should be aware that the agency is exercising its enforcement discretion as described previously only in regard to unapproved drug products containing hydrocodone that are marketed under an NDC number listed with the agency on the effective date of this notice. Unapproved drug products containing hydrocodone that are not currently marketed, or that are currently marketed but are not listed with the agency on the effective date of this notice, must, as of the effective date of this notice, have approved applications prior to their introduction or delivery for introduction into interstate commerce. Moreover, submission of an application does not excuse timely compliance with this notice.

C. Discontinued Products

Some firms may have previously discontinued the manufacturing or distribution of products covered by this notice without removing them from the listing of their products under section 510(j) of the act. Other firms may discontinue manufacturing or marketing listed products in response to this notice. Firms that wish to notify the agency of product discontinuation should send a letter, signed by the firm's chief executive officer, fully identifying the discontinued product(s), including the product NDC number(s), and stating that the product(s) has (have) been discontinued. The letter should be sent to Jennifer Devine (see **ADDRESSES**) with a copy to the district director of the firm's FDA district office. Firms should also update the listing of their product(s) under section 510(j) of the act to reflect discontinuation of unapproved hydrocodone products. FDA plans to rely on its existing records, the results of a subsequent inspection, or other available information when we evaluate whether to initiate enforcement action.

[7]For example, if a person is marketing an unapproved product containing both hydrocodone bitartrate and timed-release guaifenesin on or after August 27, 2007, then under the notice FDA issued May 29, 2007 (72 FR 29517), that person is subject to immediate enforcement; FDA will not extend the exercise of its enforcement discretion to the later dates set out in this notice.

D. Reformulated Products

In addition, FDA cautions firms against reformulating their products into unapproved new drugs without hydrocodone that are marketed under the same name or substantially the same name (including a new name that contains the old name) in anticipation of an enforcement action based on this notice. In the Marketed Unapproved Drugs CPG, FDA stated that it intends to give higher priority to enforcement actions involving unapproved drugs that are reformulated to evade an anticipated FDA enforcement action. In addition, reformulated products marketed under a name previously identified with a different active ingredient, or combination of active ingredients, have the potential to confuse healthcare practitioners and harm patients.

This notice is issued under sections 502 and 505 of the act (21 U.S.C. 352) and under authority delegated to the Deputy Commissioner for Policy under section 1410.10 of the FDA Staff Manual Guide.

Dated: September 25, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–19340 Filed 9–28–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007P–0074]

Joint Meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of a joint meeting of the Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee. This meeting was announced in the **Federal Register** of August 16, 2007 (72 FR 46091). The amendment is being made to reflect a change in the *Procedure* portion of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Darrell Lyons, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5630 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *darrell.lyons@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), codes 3014512541 and 8732310001. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 16, 2007, FDA announced that a joint meeting of Nonprescription Drugs Advisory Committee and the Pediatric Advisory Committee would be held on October 18 and 19, 2007. On page 46091, in the third column, the third sentence of the *Procedure* portion of the document is changed to read as follows:

Procedure: Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 10:30 a.m. on October 19, 2007.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: September 23, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–19332 Filed 9–28–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Board of Scientific Counselors for Clinical Sciences and Epidemiology National Cancer Institute.

The meetings will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Cancer Institute, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors for Clinical Sciences and Epidemiology National Cancer Institute.

Date: November 5, 2007.

Time: 9 a.m. to 2 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.