

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0100]

Drugs for Human Use; Unapproved and Misbranded Oral Drugs Labeled for Prescription Use and Offered for Relief of Symptoms of Cold, Cough, or Allergy; 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 against unapproved and misbranded oral drug products that are labeled for prescription use and offered for relief of symptoms of cold, cough, or allergy and persons who manufacture or cause the manufacture of such products. These drug products are marketed without approved applications, and many are inappropriately labeled for use in infants and young children. These drug products must obtain FDA approval of a new drug application (NDA) or an abbreviated new drug application (ANDA), or comply with an FDA over-the-counter (OTC) drug final monograph, before marketing.

DATES: This notice is effective March 3, 2011. For information about enforcement dates, see **SUPPLEMENTARY INFORMATION**, section IV.

ADDRESSES: All communications in response to this notice should be identified with Docket No. FDA-2011-N-0100 and directed to Sakineh Walther, Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993-0002.

FOR FURTHER INFORMATION CONTACT: Sakineh Walther, Division of New Drugs and Labeling Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5242, Silver Spring, MD 20993-0002, 301-796-3349, e-mail: sakineh.walther@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Cold, Cough, and Allergy Products Covered by This Notice

This **Federal Register** notice covers certain unapproved and misbranded drug products that are available in oral form and labeled for prescription use.

These products are offered for relief of symptoms relating to cold, cough, or allergy, and include antitussives, expectorants, antihistamines, and nasal decongestants. This notice covers extended-release,¹ tannate, and immediate-release drug products.

B. Regulatory History of Products Covered by This Notice

Many of the drug products covered by this notice contain active ingredients that were introduced into the marketplace without prior review for effectiveness. When initially enacted in 1938, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) required that FDA review and approve “new drugs” for safety, but not effectiveness, before they could legally be sold in interstate commerce.² The FD&C 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)³ 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 FD&C 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 effectiveness for all drugs approved as safe between 1938 and 1962. FDA contracted with the National Academy of Sciences/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that had been approved only for safety between 1938 and 1962. 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. FDA’s administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study

¹ The term “extended-release” is used in this document to include all timed-release products, including products labeled as “sustained-release,” “controlled-release,” “delayed-release,” or “long-acting.” (See 21 CFR 310.502(a)(14).)

² A “new drug” is defined by the FD&C Act as a drug that is not generally recognized, by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling (section 201 of the FD&C Act (21 U.S.C. 321(p)).

³ FDA’s regulations at (21 CFR 310.6(b)(1)) provide: “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 or known pharmacological properties.”

Implementation (DESI). DESI covered the approximately 3,400 products specifically reviewed by the NAS/NRC, as well as the even larger number of IRS products that entered the market without FDA approval.⁴ Many of the drug products covered by this notice contain the same active ingredients as drug products that were reviewed for effectiveness through the DESI process.

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

In the early 1970s, FDA granted temporary exemptions from the time limits established for completing certain phases of the DESI program for certain oral prescription drugs offered for relief of cold, cough, allergy, and related symptoms (38 FR 34481, December 14, 1973). The exemptions were granted because of the close relationship between these prescription drugs and OTC drugs, which were subject to the ongoing OTC drug review. (See 21 CFR part 330.) Postponement of final evaluations of these DESI prescription products enabled the Agency to consider the recommendations of the OTC review panel in addition to any evidence submitted by NDA holders and other parties in response to various DESI notices covering relevant products.

II. Safety Concerns With Unapproved New Drugs

Because marketed unapproved new drug products have not been through

⁴ Section 310.6(b)(2)) provides that when qualified experts determine that the findings in a DESI notice are applicable to an IRS drug, that IRS drug is affected by the DESI notice.

FDA's approval process, there may be safety risks associated with them. Some unapproved product labeling omits or modifies safety warnings or other information that is important to ensure safe use, such as drug interactions or potential adverse experiences. FDA is particularly concerned about pediatric labeling for these unapproved products. Some of the unapproved products covered by this notice are labeled and marketed for use in children as young as 1 month of age. Without reviewing applications for these products, FDA has no way to assess the scientific support, if any, for the use of these products in pediatric populations.

FDA also has concerns regarding the manufacturing processes for unapproved new drugs and changes in the formulations of these products. When new drugs are marketed without FDA approval, FDA does not have an opportunity, prior to product marketing, to determine whether the manufacturing process for the drugs is adequate to ensure that they are of suitable quality. Additionally, there is no opportunity prior to marketing for FDA to review and approve proprietary names to minimize potential safety issues caused by product name confusion. In fact, FDA has received reports of name confusion associated with unapproved prescription products covered by this notice. Look-alike and sound-alike similarities between product names may contribute to medication errors and adverse events.

Similarly, the new 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 effectiveness and to ensure that formulation changes are accompanied, as necessary, by appropriate changes in product proprietary names or labeling, or other measures that may be warranted to minimize confusion and risks to patients. Modifications of product formulations that are not made under FDA's drug approval process thus pose an increased risk of confusing healthcare practitioners and causing harm to consumers, such as underdose or overdose, particularly in pediatric patients.

Finally, FDA has specific safety concerns about the products covered by this notice that are marketed as extended-release products. Many of these products contain amounts of active ingredients that could pose safety risks if the same amount of active ingredient were contained in an immediate-release dosage form. Without prior review of applications for these

products, there is no assurance that the firms that market these products have established appropriate specifications for release of the active ingredients or that the products are properly formulated and manufactured to release their active ingredients to an extent and at a rate that is both safe and effective.

III. Legal Status of Products Identified in This Notice

A. Extended-Release Products

Some of the products covered by this notice are sold as extended-release products. Since 1959, FDA has concluded that all products in extended-release dosage forms are new drugs requiring approved NDAs or ANDAs before being marketed (24 FR 3756, May 9, 1959). Agency review of individual applications for extended-release products is needed to ensure that the finished product releases its active ingredient to an extent and at a rate that is both safe, with a predictable and controlled release of the dose, and effective, sustaining the intended effect over the entire dosing interval. Firms submitting applications are required to establish appropriate release specifications supported by clinical evidence, along with data showing that the finished product as manufactured by the firm releases its active ingredient according to those specifications.

The Agency's determination that all products in timed-release dosage form are new drugs requiring approved applications is codified at 21 CFR 310.502(a)(14). Approval of an NDA under section 505(b) of the FD&C Act (21 U.S.C. 355(b)) or an ANDA under section 505(j) of the FD&C Act is required as a condition for marketing all such products.

The unapproved extended-release drug products subject to this notice are all labeled for prescription use. Prescription drugs are defined under section 503(b)(1)(A) of the FD&C Act (21 U.S.C. 353(b)(1)(A)) as drugs that, because of toxicity or other potentially harmful effect, are not safe to use except under the supervision of a practitioner licensed by law to administer such drugs.⁵ A drug that is labeled as a prescription drug but does not meet the definition of "prescription drug" under section 503(b)(1)(A) of the FD&C Act is misbranded under section 503(b)(4)(B) of the FD&C Act (21 U.S.C. 353(b)(4)(B)). Thus, if an extended-release drug

⁵ The definition of "prescription drug" also includes a drug that is limited by an approved application to use under the professional supervision of a licensed practitioner (21 U.S.C. 353(b)(1)(B)). This prong of the definition obviously does not apply to the unapproved extended-release drug products covered by this notice.

covered by this notice is labeled as a prescription product, but does not meet the definition in section 503(b)(1)(A) of the FD&C Act, it is misbranded under section 503(b)(4)(B) of the FD&C Act. If an extended-release drug subject to this notice actually meets the definition of "prescription drug" under 503(b)(1)(A), it is misbranded under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), in that it fails to bear adequate directions for use. An approved prescription drug can satisfy the "adequate directions for use" requirement if it bears the NDA-approved labeling (§§ 201.100(c)(2) and 201.115 (21 CFR 201.100(c)(2) and 201.115)). Because the unapproved prescription extended-release drug products covered by this notice do not have approved applications with approved labeling, they fail to bear "adequate directions for use," and are misbranded under section 502(f)(1) of the FD&C Act.

B. Tannates

Some of the products covered by this notice contain active ingredients that are in tannate salt form (tannate drugs). FDA has reviewed the publicly available scientific literature on these ingredients, and has determined that unapproved oral drugs labeled for prescription use and offered for relief of symptoms of cold, cough, or allergy that contain the following ingredients are not generally recognized as safe and effective (GRASE): Brompheniramine tannate; carbetapentane tannate; carbinoxamine tannate; chlorpheniramine tannate; dexbrompheniramine tannate; dexchlorpheniramine tannate; dextromethorphan tannate; diphenhydramine tannate; ephedrine tannate; phenylephrine tannate; pseudoephedrine tannate; pyrilamine tannate; and triprolidine tannate. Therefore, products containing these ingredients are new drugs within the meaning of section 201(p) of the FD&C Act, and require approved NDAs or ANDAs before marketing.

The unapproved tannate drug products subject to this notice are all labeled for prescription use. Prescription drugs are defined under section 503(b)(1)(A) of the FD&C Act as drugs that, because of toxicity or other potentially harmful effect, are not safe to use except under the supervision of a practitioner licensed by law to administer such drugs.⁶ A drug that is

⁶ The definition of "prescription drug" also includes a drug that is limited by an approved application to use under the professional supervision of a licensed practitioner (21 U.S.C. 353(b)(1)(B)). This prong of the definition obviously

labeled as a prescription drug but does not meet the definition of “prescription drug” under section 503(b)(1)(A) of the FD&C Act is misbranded under section 503(b)(4)(B) of the FD&C Act. Thus, if a tannate drug covered by this notice is labeled as a prescription product, but does not meet the definition in section 503(b)(1)(A) of the FD&C Act, it is misbranded under section 503(b)(4)(B) of the FD&C Act. If a tannate drug covered by this notice actually meets the definition of “prescription drug,” it is misbranded under section 502(f)(1) of the FD&C Act, in that it fails to bear adequate directions for use. An approved prescription drug can satisfy the “adequate directions for use” requirement if it bears the NDA-approved labeling (21 CFR 201.100(c)(2) and 201.115). Because the unapproved prescription tannate drug products covered by this notice do not have approved applications with approved labeling, they fail to bear “adequate directions for use,” and are misbranded under section 502(f)(1) of the FD&C Act.

C. Immediate-Release Products

The remaining unapproved oral products covered by this notice are immediate-release products labeled for prescription use and offered for relief of symptoms associated with cold, cough, or allergy. The immediate-release products fall into the following three categories:

1. Drugs Inappropriately Labeled for Prescription Use

A small number of the immediate-release products covered by this notice conform to the requirements of the final OTC monograph at 21 CFR part 341, “Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use” (the final OTC Cold Cough monograph), except that they are labeled for prescription use only. Section 503(b)(1) of the FD&C Act establishes the definition of a “prescription drug.” Drug products that do not meet the definition of a prescription drug but are labeled for prescription use are misbranded under section 503(b)(4)(B) of the FD&C Act. If these drugs conform to the requirements of the final OTC Cold Cough monograph, they are not new drugs and they do not require an approved NDA or ANDA in order to be legally marketed OTC.⁷

does not apply to the unapproved tannate drug products covered by this notice.

⁷In addition to any other applicable requirements, firms that manufacture OTC drugs must comply with the labeling requirements at 21 CFR 201.66.

2. Drugs Containing Ingredients Included in the Final OTC Cold Cough Monograph But Labeled With Nonconforming Indications or Dosing Regimens

The majority of the immediate-release products covered by this notice are labeled for prescription use and contain ingredients that are included in the final OTC Cold Cough monograph, but have indications, dosing regimens, or both, that are inconsistent with that monograph. FDA has reviewed the indications and dosing regimens (dosing intervals and dosage amounts) in the labeling of over 300 such products, and has reviewed the publicly available scientific literature for studies of these products.⁸ In no case did FDA find literature sufficient to support a determination that one of these products was GRASE for relief of symptoms of cold, cough, or allergy. Therefore, these products are all “new drugs” within the meaning of section 201(p) of the FD&C Act, that require approved NDAs or ANDAs before marketing.

The unapproved immediate-release drug products subject to this notice that contain ingredients that are included in the final OTC Cold Cough monograph, but with indications, dosing regimens, or both, that are inconsistent with that monograph, are all labeled for prescription use. Prescription drugs are defined under section 503(b)(1)(A) of the FD&C Act as drugs that, because of toxicity or other potentially harmful effect, are not safe to use except under the supervision of a practitioner licensed by law to administer such drugs.⁹ A drug that is labeled as a prescription drug but does not meet the definition of “prescription drug” under section 503(b)(1)(A) of the FD&C Act is misbranded under section 503(b)(4)(B) of the FD&C Act. Thus, if an immediate-release drug covered by this notice is labeled as a prescription product, but does not meet the definition in section 503(b)(1)(A), it is misbranded under section 503(b)(4)(B). If an immediate-release drug covered by this notice does meet the definition of “prescription drug” in 503(b)(1)(A), it is misbranded under section 502(f)(1) of the FD&C Act,

⁸The over 300 products reviewed by FDA represent all products in this category that FDA was able to identify.

⁹The definition of “prescription drug” also includes a drug that is limited by an approved application to use under the professional supervision of a licensed practitioner (21 U.S.C. 353(b)(1)(B)). This prong of the definition obviously does not apply to the unapproved immediate-release drug products subject to this notice and containing ingredients that are included in the final OTC Cold Cough monograph, but with indications, dosing regimens, or both, that are inconsistent with that monograph.

in that it fails to bear adequate directions for use. An approved prescription drug can satisfy the “adequate directions for use” requirement if it bears the NDA-approved labeling (§§ 201.100(c)(2) and 201.115). Because the unapproved prescription immediate-release drug products subject to this notice that contain ingredients that are included in the final OTC Cold Cough monograph, but with indications, dosing regimens, or both, that are inconsistent with that monograph, do not have approved applications with approved labeling, they fail to bear “adequate directions for use,” and are misbranded under section 502(f)(1).

3. Drugs Containing Ingredients Not Included in the Final OTC Cold Cough Monograph

The remaining immediate-release products covered by this notice are labeled for prescription use and contain active ingredients that are not included in the final OTC Cold Cough monograph. FDA has reviewed the publicly available scientific literature on these ingredients, and has determined that the products covered by this notice and offered for relief of symptoms of cold, cough, or allergy that contain the following ingredients are not GRASE: Atropine; carbetapentane; cyproheptadine; dyphylline; hyoscyamine; methscopolamine nitrate; phenyltoloxamine; potassium guaiacosulfonate; promethazine; and scopolamine. Therefore, products covered by this notice containing these ingredients and marketed for relief of symptoms of cold, cough, or allergy are new drugs within the meaning of section 201(p) of the FD&C Act, and require approved NDAs or ANDAs prior to marketing.

The unapproved immediate-release drug products that are subject to this notice and that contain active ingredients not included in the final OTC Cold Cough monograph are all labeled for prescription use. Prescription drugs are defined under section 503(b)(1)(A) of the FD&C Act as drugs that, because of toxicity or other potentially harmful effect, are not safe to use except under the supervision of a practitioner licensed by law to administer such drugs.¹⁰ A drug that is

¹⁰The definition of “prescription drug” also includes a drug that is limited by an approved application to use under the professional supervision of a licensed practitioner (21 U.S.C. 353(b)(1)(B)). This prong of the definition obviously does not apply to the unapproved immediate-release drug products covered by this notice that contain active ingredients not included in the final OTC Cold Cough monograph.

labeled as a prescription drug but does not meet the definition of "prescription drug" under section 503(b)(1)(A) is misbranded under section 503(b)(4)(B) of the FD&C Act. Thus, if an immediate-release drug covered by this notice is labeled as a prescription product, but does not meet the definition in section 503(b)(1)(A), it is misbranded under section 503(b)(4)(B). If a drug covered by this notice meets the definition of "prescription drug" in 503(b)(1)(A), it is misbranded under section 502(f)(1) of the FD&C Act, in that it fails to bear adequate directions for use. An approved prescription drug can satisfy the "adequate directions for use" requirement if it bears the NDA-approved labeling (§§ 201.100(c)(2) and 201.115). Because the unapproved prescription immediate-release drug products covered by this notice that contain active ingredients not included in the final OTC Cold Cough monograph do not have approved applications with approved labeling, they fail to bear "adequate directions for use," and are misbranded under section 502(f)(1) of the FD&C Act.

IV. Notice of Enforcement Action

Although not required to do so by the Administrative Procedure Act, the FD&C Act, or any rules issued under its authority, or for any other legal reason, FDA is providing this notice to persons¹¹ who are marketing unapproved and misbranded oral drug products labeled for prescription use and offered for relief of symptoms relating to cold, cough, or allergy 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.

Manufacturing or shipping the drug products covered by this notice can result in enforcement action, including seizure, injunction, or other judicial or administrative proceeding. Consistent with policies described in the Agency's guidance entitled "Marketed Unapproved Drugs—Compliance Policy Guide" (the Marketed Unapproved Drugs CPG) (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf>), the Agency does not expect to issue a warning letter or any other further warning to firms marketing drug products covered by this notice 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 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.¹²

As described in the Marketed Unapproved Drugs CPG, the Agency may, at its discretion, identify a period of time during which the Agency does not intend to initiate an enforcement action against a currently marketed unapproved drug solely on the ground that it lacks an approved application under section 505 of the FD&C Act. With respect to drug products covered by this notice, the Agency intends to exercise its enforcement discretion for only a limited period of time because there are safety issues with respect to the products covered by this notice and numerous marketed products that have approved applications or comply with the applicable OTC drug final monograph are offered to treat symptoms relating to cold, cough, and allergy. Therefore, the Agency intends to implement this notice as follows.

For the effective date of this notice, see the **DATES** section of this document. FDA intends to take enforcement action against any drug product covered by this notice that is not listed with the Agency in full compliance with section 510 of the FD&C Act (21 U.S.C. 360) before March 2, 2011, and is manufactured, shipped, or otherwise introduced or delivered for introduction into interstate commerce by any person on or after March 3, 2011. FDA also intends to take enforcement action against any drug product covered by this notice that is listed with FDA in full compliance with section 510 of the FD&C Act but is not being commercially used or sold¹³ in the United States on March 2, 2011 and that is manufactured, shipped, or otherwise introduced or delivered for introduction into interstate commerce by any person on or after March 3, 2011.

However, for drug products covered by this notice that are commercially used or sold in the United States, have a National Drug Code (NDC) number listed with FDA, and are in full

compliance with section 510 of the FD&C Act before March 2, 2011 ("currently marketed and listed"), the Agency intends to exercise its enforcement discretion as follows. FDA intends to initiate enforcement action against any currently marketed and listed product covered by this notice that is manufactured on or after June 1, 2011 or that is shipped on or after August 30, 2011.¹⁴ Further, FDA intends to take enforcement action against any person who manufactures or ships such products after these dates. Any person who has submitted or submits an application for a drug product covered by this notice but has not received approval must comply with this notice.

The Agency, however, does not intend to exercise its enforcement discretion as outlined previously if the following apply: (1) A manufacturer or distributor of drug products covered by this notice is violating other provisions of the FD&C Act, including, but not limited to, violations related to FDA's current good manufacturing practices, adverse drug event reporting, labeling or misbranding requirements other than those identified in this notice or (2) it appears that a firm, in response to this notice, increases its manufacture or interstate shipment of drug products covered by this notice above its 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 FD&C Act, whether or not related to a drug product covered by this notice. Similarly, a person who is or becomes enjoined from marketing unapproved or misbranded drugs may not resume marketing of such products based on FDA's exercise of enforcement discretion that is set forth in this notice.

Drug manufacturers and distributors should be aware that the Agency is exercising its enforcement discretion as described previously only in regard to

¹⁴ 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 FD&C 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").)

¹² The Agency's general approach for 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.

¹³ For purposes of this notice, the term "commercially used or sold" means that the product has been used in a business or activity involving retail or wholesale marketing and/or sale.

¹¹ A "person" includes individuals, partnerships, corporations, and associations (21 U.S.C. 321(e)).

drug products covered by this notice that are marketed under an NDC number listed with the Agency in full compliance with section 510 of the FD&C Act before March 2, 2011. As previously stated, drug products covered by this notice that are currently marketed but not listed with the Agency on the date of this notice must, as of the effective date of this notice, have approved applications prior to their shipment in interstate commerce. Moreover, any person or firm that has submitted or submits an application but has yet to receive approval for such products is still responsible for full compliance with this notice.

V. 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 FD&C 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 NDC number(s), and stating that the product(s) has (have) been discontinued. The letter should be sent to Sakineh Walther (*see ADDRESSES*). Firms should also update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of products covered by this notice. FDA plans to rely on its existing records, including its drug listing records, or other available information when it targets violations for enforcement action.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sections 502 and 505 (21 U.S.C. 352 and 355)) and under authority delegated to the Assistant Commissioner for Policy under section 1410.21 of the FDA Staff Manual Guide.

Dated: February 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-4703 Filed 3-2-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation; Notice of Meeting

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Health Resources and Services Administration published a notice in the **Federal Register** of February 9, 2011 (76 FR 7223-7224) announcing an Advisory Committee on Organ Transplantation meeting on March 8, 2011. The type of meeting, time and place have been changed.

Correction

In the **Federal Register** of February 9, 2011, in FR Doc. 2011-2839, on page 7223, 2nd column, under the heading Department of Health and Human Services, Health Resources and Services Administration, Advisory Committee on Organ Transplantation; Notice of Meeting, change the Times and Place to read:

The meeting will be an Audio Conference Call on March 8, 2011, from 12 noon to 4 p.m. EST. To access the conference call, call the USA Toll Free Number 888-469-1090 and enter the Passcode 2741198. The conference call leader is Patricia A. Stroup. Participants should call no later than 11:45 a.m. EST in order for logistics to be set up. Participants are asked to register for the conference call by contacting Brittany Carey, HRM/Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at (703) 889-9033 or b_carey@team-psa.com. The registration deadline is March 7, 2011. The Department will try to accommodate those wishing to participate in the call.

The next face-to-face ACOT meeting is planned for August 2011. Details regarding an August meeting will be published in a subsequent **Federal Register** notice.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011-4755 Filed 3-2-11; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Member Conflict.

Date: March 15, 2011.

Time: 9 a.m. to 10 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ramesh Vemuri, PhD, Chief, Scientific Review Branch, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C-212, Bethesda, MD 20892, 301-402-7700, rv23r@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: February 25, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011-4826 Filed 3-2-11; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections