Sponsor	NADA Number Product (Drug)	21 CFR Cite Affected (Sponsor Drug Labeler Code)
.....	NADA 30–330 Tylocine Sulfa Tablets (sulfadiazine, sulfamerazine, sulfamethazine, tylosin).	not applicable
.....	NADA 31–962 Tylan plus Neomycin Eye Powder (neomycin sulfate, tylosin).	524.2640 (000986)
.....	NADA 40–123 Toptic Ointment (cephalonium, flumethasone, iodochlorhydroxyquin, piperocaine hydrochloride, polymyxin B sulfate).	524.321 (000986)
.....	NADA 47–092 Tribodine (ticarbodine)	520.2460a (000986)
.....	NADA 47–353 Ferti-Cept (chorionic gonadotropin).	522.1081(b) (000986)
.....	NADA 92–602 Cephalothin Discs (cephaloridine).	529.360 (000986)
.....	NADA 96–678 Tribodine Capsules (ticarbodine).	520.2460b (000986)
Bioproducts, Inc., 320 Springside Dr., suite 300, Fairlawn, OH 44333–2435.	NADA 93–518 Tylan® 10 Plus (tylosin phosphate).	558.625(b)(2) (051359)
Young's Inc., Roaring Spring, PA 16673	NADA 96–162 Hog Grow-R-Mix-4000, Hog Grow-R-Mix–800 (tylosin phosphate).	558.625(b)(13) (035393)
Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215.	NADA 42–889 Oxytocin Injection (oxytocin)	522.1680(b) (000857)
Webel Feeds, Inc., R.R. 3, Pittsfield, IL 62363 ...	NADA 116–196 Webel Tylan Premix (tylosin phosphate).	558.625(b)(73) (035098)

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADAs 12–585, 15–207, 30–330, 31–962, 40–123, 42–889, 47–092, 47–353, 92–602, 93–518, 96–162, 96–678, and 116–196, and all supplements and amendments thereto, is hereby withdrawn, effective May 14, 2001.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations by removing those portions that reflect approval of the NADAs.

Dated: April 23, 2001.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 01–11071 Filed 5–2–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Single Source Cooperative Agreement to Support the National Center for Natural Products Research (NCNPR), University of Mississippi

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to accept and consider a single source application for the award of a cooperative agreement to the University of Mississippi (UM) to support the National Center for Natural Products Research (NCNPR), which is located on UM's Campus at Oxford, MS. FDA anticipates providing up to $1 million in fiscal year 2001 (direct and indirect costs) for this project, with an additional 4 years of funding up to $1 million per year predicated upon acceptable performance and the availability of future fiscal year funding. These collaborations will support and benefit the public health by promoting more efficient development and dissemination of natural products research and science and will complement the diverse activities of both the public and private sector that may become collaborators.

DATES: Submit applications by June 18, 2001.

ADDRESSES: An application is available from, and should be submitted to Rosemary Springer, Grants Management Specialist, Division of Contracts and Procurement Management (HFA–520), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7182, e-mail: rspringe@oc.fda.gov. Applications hand-carried or commercially delivered should be addressed to rm. 2129, 5630 Fishers Lane, Rockville, MD 20857. Application forms can also be found at http://www.nih.gov/grants/funding/phs398/forms__toc.html.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects of this notice: Rosemary Springer (address above).

Regarding the programmatic aspects: Jeanne I. Rader, Center for Food Safety and Applied Nutrition (HFS–840), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5375, e-mail: JRader@CFSAN.fda.gov.

SUPPLEMENTARY INFORMATION: FDA is announcing its intention to accept and consider a single source application from UM for a cooperative agreement to support NCNPR. FDA's authority to enter into grants and cooperative agreements is detailed under section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance at 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public.

The Public Health Service (PHS) strongly encourages all award recipients to provide a smoke-free work place and to discourage the use of all tobacco products. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

FDA is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a national activity to reduce morbidity and mortality and to improve the quality of life. Applicants may obtain a hard copy of Healthy People 2010 objectives, volumes I and II,

conference edition (B0074) for $22 per set, by writing to the Office of Disease Prevention and Health Promotion (ODPHP) Communication Support Center, P.O. Box 37366, Washington, DC 20013–7366. Each of the 28 chapters of Healthy People 2010 is priced at $2 per copy. Telephone orders can be placed to the ODPHP Center on 301–468–5690. The ODPHP Center also sells the complete conference edition in CD–ROM format (B0071) for $5. This publication is available as well on the Internet at www.health.gov/healthypeople/. Web site viewers should proceed to ''Publications.''

I. Background

Congress amended the Federal Food, Drug, and Cosmetic Act (the act) with the passage of the Dietary Supplement Health and Education Act of 1994, to create a regulatory framework for dietary supplements under food provisions of the act. FDA has primary responsibility for ensuring that appropriate regulatory actions are taken against marketed products that: (a) Present an unreasonable or significant risk of illness or injury when used according to label directions or under ordinary conditions of use, or (b) bear labeling that is false or misleading.

The ability to identify and analyze specific components in ingredients, including botanical ingredients, and in finished products is an essential component of research and regulatory programs directed at ensuring that dietary supplements are safe and that their labeling is truthful and not misleading. The availability of authenticated reference materials is an essential prerequisite to the accurate identification and quantitative analysis of ingredients or finished products. For many botanical ingredients currently used in marketed dietary supplement products, however, appropriate reference materials are not readily available, their authenticity is not well documented, and their compositional characteristics are not adequately defined and evaluated for biological effects.

The use of botanical products in dietary supplements in the U.S. has increased significantly in recent years. The newness of the regulatory approaches and marketed uses of these products has created a critical need for bringing sound science to a number of issues that are necessary to ensure that marketed products are safe and their labeling is truthful and not misleading. Therefore, it is essential that general principles and criteria for ensuring scientific validity in manufacturing of botanical products and the use of botanical ingredients in dietary supplements be developed through scientific discussion and consensus-building. Such general principles and criteria will be applicable not only to FDA regulatory and research activities, but will also promote consistency and scientific rigor with respect to research and standard-setting activities performed by other organizations and agencies, and will assist in the development of quality control practices by industry.

II. Goals and Objectives

A. Concept

FDA believes that cooperative research with the UM–NCNPR will provide opportunities to address important national and international problems in natural products research in a timely manner. However, only FDA employees will perform any official regulatory activities. Further, FDA believes that cooperative research through UM will promote the efficient use of the complementary resources of both parties.

The applicant would propose to design, implement, and evaluate a comprehensive, multidisciplinary array of scientific activities in the broad area of natural products' ingredients. The applicant's proposal must be designed to meet the objectives of the request for applications (RFA). The applicant's proposal should identify and assess innovative approaches to address the RFA objectives relative to the broad area of natural product identification and safety.

The purpose of this cooperative agreement would be to:

- Coordinate scientific workshops and conferences on relevant topics of public interest to address high priority science and research needs;
- Obtain and characterize authenticated reference materials for botanicals;
- Develop literature reviews on relevant topics; and
- Share technical information and scientific concepts.

B. Project Emphasis

The purpose is to augment and enhance research and scientific expertise in natural products research. There is a critical need to address the increasingly complex problems in such areas as acquisition, validation, and characterization of botanical reference materials, related research and literature reviews to ensure the safety or effectiveness of marketed products, and the development of sound scientific principles and consensus-building for dealing with these ingredients and products. Since there is increased concern regarding the safety of dietary supplements, the need to find other ways of expanding the current science base is essential.

The sharing of complementary resources will create opportunities for important national and international issues in natural products research to be addressed in a timely and scientifically sound manner. Many of these issues (e.g., development and characterization of authenticated botanical reference standards, and scientific review and consensus-building) can only be addressed with close cooperation of the public and private sectors. UM's expertise and facilities for obtaining and characterizing authenticated botanical reference materials are needed to conduct investigations at the forefront of natural products research. Additionally, UM's experimental field plots, vast repository containing thousands of natural products extracts for testing in a variety of biological assays, and their expertise and long history of active scientific investigations are well known in these areas. University personnel will provide enhanced scientific expertise in advanced techniques for the characterization of natural products as well as expand the current capabilities in research to support regulatory actions and respond to emergency situations.

C. Summary

FDA believes that research conducted at the UM is a sound investment in the future public health of American consumers. It provides an opportunity for extensive cooperation with university scientists; and it will stimulate collaborative efforts to ensure a safe food supply contributing significantly to the implementation of the goals for government, academia, industry, and consumers to work together to improve the safety of natural products. The UM scientists would bring a special perspective to advancing the knowledge of natural products germane to the public interest. Interaction among those scientists will stimulate creativity and innovation. FDA's participation in this venture will promote a greater awareness and understanding of regulatory science and practice among academic scientists, thereby providing economic and program benefits to both. In summary, collaboration between the public and the private sector provides an efficient means of remaining current with scientific and technical accomplishments in the areas of natural products research.

III. Mechanism of Support

A. Award Instrument

Support for this program, if awarded, will be in the form of a cooperative agreement. The award will be subject to all policies and requirements that govern the research grant programs of the PHS, including the provisions of 42 CFR part 52, 45 CFR parts 74 and 92, and PHS's grants policy statement. The regulations issued under Executive Order 12372 do not apply.

B. Length of Support

The length of support will be for 1 year with the possibility of an additional 4 years of noncompetitive support. Continuation, beyond the first year, will be based upon performance during the preceding year and the availability of Federal fiscal year appropriations. The National Institutes of Health (NIH) modular grant program does not apply to this FDA program.

IV. Reasons for Single Source Selection

Competition is limited to UM because: (1) FDA's appropriations language has included funds for collaborative research on dietary supplements between UM–NCNPR and FDA; and (2) UM has been determined to be the only institution with the unique capability of providing a broad range of highly relevant scientific expertise and facilities that are physically co-located and singularly dedicated to natural products research.

FDA believes that there is compelling evidence that UM is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. UM is a comprehensive research institution with numerous academic programs relevant to natural products which can help to ensure that market products are safe for the American public. The UM School of Pharmacy has been in existence for 90 years and has an outstanding 30-year track record for isolating and developing prospective new pharmaceuticals from plants and microorganisms.

NCNPR, which opened in July 1999, is a division of the Research Institute of Pharmaceutical Sciences of the UM's School of Pharmacy. NCNPR was created to bring together an alliance of academia, government, and the pharmaceutical and agrochemical industries to integrate research, development, and commercialization of potentially useful natural products. The facility is the nation's only university-affiliated research center devoted to improving human health and agricultural productivity through the discovery, development, and commercialization of pharmaceuticals and agrochemicals derived from natural products. The goal of NCNPR in botanical dietary supplements is to enable safe, effective, and proper use of high quality botanical products by informed professionals and consumers. NCNPR conducts basic and applied multidisciplinary research to discover and develop natural products for use as pharmaceuticals, dietary supplements and agrochemicals. NCNPR also maintains a repository of several thousand natural product extracts that are available for screening by collaborators working in other areas.

NCNPR has substantial expertise to carry forward specific discoveries, products, and technologies. Most of the projects to develop promising high priority products or technology are conducted in collaboration with industrial partners or through externally funded grants and contract. NCNPR is staffed with a highly synergistic mix of full-time research faculty and support staff and employs a number of undergraduate and graduate students and postdoctoral scientists. Additionally, the USDA's National Products Utilization Research Unit is co-housed and programmatically integrated with the NCNPR thus expanding the available expertise and facilities. Together, the faculty, scientists, staff, students, USDA scientists, and external collaborators, provide the human resources required to accomplish the research and development goals of the RFA.

Additionally, FDA's appropriations language includes funds for collaborative research on dietary supplements between NCNPR and FDA. NCNPR has the unique capability to bring together diverse scientific expertise on bioactive natural products research from: (a) The UM faculty in the School of Pharmacy involving researchers in the Departments of Pharmacognosy, Medicinal Chemistry, Pharmaceutics, Pharmacology, and the Research Institute of Pharmaceutical Sciences; (b) research scientists in the U.S. Department of Agriculture/Agricultural Research Service's (USDA/ARS) National Products Utilization Research Unit who are physically co-housed and programmatically integrated in the NCNPR; and (c) its close academic links and historical collaborations with agricultural and botanical programs and facilities at the UM system. UM–NCNPR's ability to successfully and uniquely collaborate with FDA is also enhanced by its a repository of several thousand natural product extracts; and its long history of successful basic and applied multidisciplinary research to discover and develop natural products for use as bioactive ingredients in dietary supplements and pharmaceuticals, and for improving the quality and safety of dietary supplements. Finally, the large number of established collaborations among NCNPR scientists and other government agencies, academic organizations, and research institutions will also be useful in enhancing the collaborative efforts with FDA. These collaborations will support and benefit the public health by promoting more efficient development and dissemination of natural products research and science and will complement the diverse activities of both the public and private sector that may become collaborators.

Research in NCNPR is focused on using state-of-the-art knowledge and technology to discover bioactive natural products, develop novel technologies or processes that facilitate the discovery of bioactive natural products, and provide research-based information on plant derived products with health applications. These programs, facilities, and expertise are essential for supporting the needs to ensure that sound science is available for ensuring the safety and truthfulness of labeling of marketed dietary supplement products.

Collaboration between the public and private sector is an efficient means for both FDA and UM to remain current with scientific and technical accomplishments from a natural products research perspective. Harmonizing regulatory activities is but one example of the need for and use of this natural products research knowledge and expertise. The partnership between FDA and UM will provide both the technical and educational expertise necessary for effective mechanisms that will facilitate the movement of new technology and provide direct usefulness to the public health.

V. Reporting Requirements

An annual financial status report (FSR) (SF–269) is required. The original and two copies of this report must be submitted to FDA's Grants Management Officer within 90 days of the budget expiration date of the grant. Failure to file the FSR in a timely fashion will be grounds for suspension or termination of the grant.

An annual program progress report is also required. The noncompeting continuation application (PHS 2590) will be considered the annual program progress report. The progress report must include a description of the progress and accomplishments for each objective stated in the RFA.

A final program progress report, FSR (SF–269), and invention statement must be submitted within 90 days after the expiration of the project period as noted on the notice of grant award.

VI. Delineation of Substantive Involvement

Substantive involvement by the awarding agency is inherent in the cooperative agreement award. Accordingly, FDA will have substantial involvement in the program activities of the project funded by the cooperative agreement. Substantive involvement includes, but is not limited to, the following:

1. FDA will work closely with the grantee and have final approval on all project activities. This could include management structure for the program, development of plans and strategies for key scientific approaches and projects, and for identifying and carrying out the research.

2. FDA will participate in all functions directly related to the guidance and development of the program.

3. FDA will provide technical monitoring and/or direction of the work, including monitoring of data analysis, interpretation of analytical findings and their significance.

4. FDA will assist and approve (as deemed appropriate) the substance of publications, co-authorship of publications and data release.

5. FDA will have final approval on any re-directions proposed during the course of the project.

VII. Review Procedures

A. Review Method

The application submitted in response to this RFA will first be reviewed by grants management and program staff for responsiveness. The application will be considered nonresponsive if it is not in compliance with this document. If an application is found to be nonresponsive it will be returned to the applicant without further consideration. An application is considered nonresponsive for the following reasons: (1) The applicant organization is ineligible; (2) it is received after the specified receipt date; (3) it is incomplete; (4) it is illegible; (5) it is not responsive to the RFA; (6) the material presented is insufficient to permit an adequate review; and/or (7) it exceeds the recommended threshold amount reflected in the RFA.

A responsive application will be reviewed and evaluated for scientific and technical merit by an ad hoc panel of experts in the subject field. A responsive application will also be subject to a second level of review by a National Advisory Council for concurrence with the recommendations made by the first level reviewers. The Commissioner of FDA or his/her designee will make final funding decisions.

B. Review Criteria

1. Responsiveness to RFA

The application must demonstrate that the objectives and goals of the RFA are understood and the applicant shall offer a logical program to meet the objectives of the RFA.

2. Adequacy of Plan

The applicant must provide a detailed plan to establish a collaborative natural products research program as a multidisciplinary effort (i.e., FDA and academia). The application will be evaluated on the thoroughness of the plan, the reasonableness of the approach, and adherence to the concept and its objectives, as stated in the RFA. The detailed plan must form the basis of a balanced natural products research program directed toward development of skills and expertise in aspects of natural products research, as stated in the RFA. Included will be development of: Scientific expertise in natural products research involving researchers in pharmacognosy, medicinal chemistry, pharmacology, and pharmaceutical sciences; state of the art knowledge and technology to discover bioactive natural products; novel technologies or processes that facilitate the discovery of bioactive natural products; and research-based information on potential health applications of plant derived products. The plan must also include a schedule for accomplishing the objectives outlined above.

3. Timeliness of Program Implementation

The application will be evaluated for the applicant's ability to establish natural products research in an expeditious manner.

4. Adequacy and availability of research facilities

The application must demonstrate that the applicant has adequate research facilities in the areas of: Pharmacognosy, medicinal chemistry, pharmacology, and pharmaceutical sciences, as stated in the RFA.

5. Ability to Conduct Proprietary Research

The application shall demonstrate the applicant's ability to conduct proprietary research and to protect confidentiality of data, procedures, etc.

6. Staff Experience and Capabilities

The application must demonstrate the availability of core staff with the experience and capability to conduct research as described in the detailed plan presented in item 2 above. The staff must have the capability to deal with natural products research as well as plan long-range research to assess future needs. The availability of sufficient administrative and support personnel to meet the RFA objectives must also be demonstrated.

7. Reasonableness of proposed budget

The application is evaluated on the bases of the reasonableness of costs.

VIII. Submission Requirements

The original and two copies of the completed grant application form PHS 398 (Rev. 4/98), with appendices for each of the copies, should be delivered to Rosemary Springer (address above). The application receipt date is June 18, 2001. No supplemental or addendum material will be accepted after the receipt date. The outside of the mailing package and item 2 of the application face page should be labeled: ''Response to RFA–FDA–CFSAN–2001–2.''

IX. Method of Application

A. Submission Instructions

Applications will be accepted during normal business hours, 8 a.m. to 4:30 pm., Monday through Friday, on or before the established receipt date. Applications will be considered received on time if sent or mailed on or before the receipt date as evidenced by a legible U.S. Postal Service dated postmark or a legible date receipt from a commercial carrier, unless they arrive too late for orderly processing. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications not received on time will not be considered for review and will be returned to the applicant. (Applicants should note that the U.S. Postal Service does not uniformly provide dated postmarks. Before relying on this method, applicants should check with their local post office.) Do not send applications to the Center for Scientific Research (CSR), NIH. Any application that is sent to NIH, that is then forwarded to FDA and not received in time for orderly processing, will be deemed nonresponsive and returned to the applicant. Applications must be submitted via mail delivery as stated above. FDA is unable to receive applications electronically. Instructions for completing the application form can

be found on the following Web site: http://www.nih.gov/grants/funding/phs398/phs398.html. The forms can be found at http://www.nih.gov/grants/funding/phs398/forms__toc.html. Applicants are advised that FDA does not adhere to the page limitations or the type size and line spacing requirements imposed by NIH on its applications.

B. Format for Application

Submission of the application must be on Grant Application Form PHS 398 (Rev. 4/98). All ''General Instructions'' and ''Specific Instructions'' in the application kit should be followed with the exception of the receipt dates and mailing label address. The face page of the application should reflect the request for applications number RFA–FDA–CFSAN–2001–2.

Data included in the application, if restricted with the legend specified below, may be entitled to confidential treatment as trade secret or confidential commercial information within the meaning of the Freedom of Information Act (5 U.S.C. 552(b)(4)) and FDA's implementing regulations (21 CFR 20.61).

Information collection requirements requested on Form PHS 398 and the instructions have been submitted by PHS to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

C. Legend

Unless disclosure is required by the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of DHHS or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information shall not be used or disclosed except for evaluation purposes.

Dated: April 30, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–11159 Filed 5–2–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Anesthetic and Life Support Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anesthetic and Life Support Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 14 and 15, 2001, 8 a.m. to 5 p.m.

Location: Holiday Inn, The Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Kimberly Topper, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–7001, e-mail: topperk@cder.fda.gov, FAX 301–827–6801, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12529. Please call the Information Line for up-to-date information on this meeting.

Agenda: On both days the committee will discuss the medical use of opiate analgesics in various patient populations, including pediatric patients and patients with chronic pain of nonmalignant etiology, as well as the risk to benefit ratio of extending opiate treatment into these populations. It will also address concerns regarding the abuse potential, diversion and increasing incidence of addiction to opiate analgesics, especially to the modified release opiate analgesics.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 7, 2001. Oral presentation from the public will be scheduled between approximately 1 p.m. and 2 p.m each day. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before June 7, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Background material from FDA will be posted 24 hours before the meeting at the Anesthetic and Life Support Drugs Advisory Committee docket site at http://www.fda.gov/ohrms/dockets/ac/acmenu.htm. (Click on the year 2001 and scroll down to Anesthetic and Life Support Drugs meetings.) This is the same Web site where you can find the minutes, transcript, and slides from the meeting. This material is generally posted about 3 weeks after the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 27, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01–11157 Filed 4–30–01; 4:16 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0184]

Compliance Policy Guide: ''Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a compliance policy guide (CPG) entitled ''Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens.'' This CPG is intended to set forth FDA's internal enforcement priorities concerning undeclared food allergens.

DATES: Submit written comments on this CPG at any time.

ADDRESSES: Submit written requests for single copies of the CPG entitled ''Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens'' to the Director, Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–827–0482. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

Submit written comments on the CPG to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Technical questions concerning allergens in foods: Kathy Gombas, Office of Field Programs (HFS–615), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4231, FAX 202–260–0136.

Questions concerning regulatory actions: MaryLynn Datoc, Office of Enforcement (HFC–230), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0413, FAX 301–827–0482.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has developed a CPG on FDA's internal enforcement process concerning undeclared allergens in