

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 materials, 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 of Mental Health Special Emphasis Panel; Fellowships and Dissertations.

*Date:* July 13, 2010.

*Time:* 1 p.m. to 3:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Serena P. Chu, PhD, Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892-9609, 301-443-0004, [sechu@mail.nih.gov](mailto:sechu@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: May 27, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-13413 Filed 6-3-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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 of Child Health and Human Development Special Emphasis Panel; Race-Based Social Stress and Health in the MADICS Longitudinal Study, University of Michigan at Ann Arbor.

*Date:* June 25, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road, NW., Washington, DC 20015.

*Contact Person:* Michele C. Hindi-Alexander, PhD, Division of Scientific Review, National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 1600 Executive Boulevard, Rm. 5B01, Bethesda, MD 20892, (301) 435-8382, [hindiadm@mail.nih.gov](mailto:hindiadm@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: May 27, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0215]

#### Substances Generally Recognized as Safe Added to Food for Animals; Notice of Pilot Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is seeking participants for a voluntary pilot program whereby persons submit to FDA notices of claims that a particular use of a substance in food for animals is exempt from the statutory premarket approval requirements based on the notifier's determination that such use is generally recognized as safe (GRAS). FDA intends to evaluate these notices and will inform each participant (notifier) in writing either that the notice provides a sufficient basis for the GRAS determination or that FDA has identified questions as to whether the intended use of the substance is GRAS.

**DATES:** Submit written requests to participate in the pilot program beginning June 4, 2010.

**ADDRESSES:** Submit written requests to participate in the pilot program to the Division of Animal Feeds (HFV-224), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.

**FOR FURTHER INFORMATION CONTACT:**

Geoffrey K. Wong, Center for Veterinary Medicine (HFV-224), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6879, [Geoffrey.wong@fda.hhs.gov](mailto:Geoffrey.wong@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

### I. Background

#### A. The 1958 Amendment

In 1958, in response to public concern about the increased use of chemicals in foods and food processing, Congress enacted the Food Additives Amendment (the 1958 amendment) to the Federal Food, Drug, and Cosmetic Act (the act). The 1958 amendment required that, before a new additive could be used in food, its producer must demonstrate the safety of the additive to FDA. The 1958 amendment defined the terms "food additive" (section 201(s) of the act (21 U.S.C. 321(s))) and "unsafe food additive" (section 409(a) of the act (21 U.S.C. 348(a))), established a premarket approval process for food additives (section 409(b) through (h)), and amended the food adulteration provisions of the act to deem adulterated any food that is, or bears or contains, any food additive that is unsafe within the meaning of section 409 (section 402(a)(2)(C) of the act (21 U.S.C. 342(a)(2)(C))).

In enacting the 1958 amendment, Congress recognized that many substances intentionally added to food would not require formal premarket review by FDA to assure their safety. Congress thus adopted, in section 201(s) of the act, a two-step definition of "food additive." The first step broadly includes any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food. The second step, however, excludes from the definition of "food additive" substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety ("qualified experts"), as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or through

experience based on common use in food) to be safe under the conditions of their intended use.

#### B. Elements of the GRAS Standard

Importantly, under section 201(s) of the act, it is the use of a substance, rather than the substance itself, that is eligible for the GRAS exemption. FDA has defined “safe” as a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use (21 CFR 570.3(i)). Current § 570.30(b) (21 CFR 570.30(b)) provides that general recognition of safety based on scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the substance. The requirement for scientific evidence of safety is referred to in this document as the “technical element” of safety. While a determination that a food additive is safe requires technical evidence of safety, a determination that a particular use of a substance is GRAS requires both technical evidence of safety and a basis to conclude that this technical element of safety is generally recognized. Such general recognition of safety requires common knowledge about the substance throughout the scientific community, so it is referred to in this document as the “common knowledge element” of the GRAS standard.

The common knowledge element of the GRAS standard includes two facets: (1) The data and information relied on to establish the technical element, which must be of the same kind and quality as is required to obtain FDA approval of the use of the substance, must be generally available and (2) there must be a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use. (See *United States v. Western Serum Co., Inc.*, 666 F.2d 335, 338 (9th Cir. 1982); *United States v. Articles of Drug \* \* \* Promise Toothpaste*, 624 F.Supp. 776, 778 (N.D. Ill. 1985), aff’d 826 F.2d 564 (7th Cir. 1987); *United States v. Articles of Drug \* \* \* Hormonin*, 498 F.Supp.2d 424, 435 (D.N.J. 1980)). None of the facets by themselves are sufficient to satisfy the common knowledge element of the GRAS standard.

The usual mechanism to establish that scientific information is generally available is to show that the information is published in a peer-reviewed scientific journal. However, mechanisms to establish the basis for concluding that there is expert consensus about the safety of a

substance are more varied. In some cases, publication in a peer-reviewed scientific journal of data (such as toxicity studies) on a substance has been used to establish expert consensus in addition to general availability. In other cases, such publication of data and information in the primary scientific literature has been supplemented by: (1) Publication of data and information in the secondary scientific literature, such as scientific review articles, textbooks, and compendia; (2) documentation of the opinion of an “expert panel” that is specifically convened for this purpose; or (3) the opinion or recommendation of an authoritative body such as the National Research Council of the National Academy of Sciences on a broad or specific issue that is related to a GRAS determination.

In this document, FDA is using the term “consensus” in discussing the common knowledge element of the GRAS standard. Such consensus does not require unanimity among qualified experts. (See *United States v. Articles of Drug \* \* \* 5,906 Boxes*, 745 F.2d 105, 119 n. 22 (1st Cir. 1984); *United States v. An Article of Drug \* \* \* 4,680 Pails*, 725 F.2d 976, 990 (5th Cir. 1984); *Coli-Trol 80, supra*, 518 F.2d at 746; *Promise Toothpaste, supra*, 624 F.Supp. at 782).

A substance used in food prior to January 1, 1958, may be shown to be GRAS for an intended use through scientific procedures or through experience based on common use in food. Current § 570.30(c) (21 CFR 570.30(c)) provides that general recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation. Current § 570.3(f) defines “common use in food” as a substantial history of consumption for food use by a significant number of animals in the United States.

#### C. History of FDA’s Approach to the GRAS Exemption

Shortly after passage of the 1958 amendment, FDA clarified the regulatory status of a multitude of food substances that were used in food prior to 1958 and amended its regulations to include a list of food substances that, when used for the purposes indicated and in accordance with current good manufacturing practices, are GRAS. This GRAS list was incorporated into the agency’s regulations as § 121.101(d) (now parts 182 and 582 (21 CFR parts 182 and 582)) (24 FR 9368, November 20, 1959). As part of that rulemaking, however, FDA acknowledged that it

would be impracticable to list all substances that are GRAS for their intended use.

In 1970, FDA announced that it was undertaking a comprehensive agency review of substances listed as GRAS (35 FR 18623, December 8, 1970). In the notice announcing this review, FDA proposed criteria that could be used to establish whether these substances should continue to be listed as GRAS, become the subject of a food additive regulation, or become the subject of an interim food additive regulation pending completion of additional studies. These criteria were incorporated into the agency’s regulations in 21 CFR 121.3 (precursor of current 21 CFR 570.30) (36 FR 12093, June 25, 1971). FDA subsequently codified procedures for the agency to affirm, on its own, the GRAS status of substances found to satisfy these criteria (§ 570.35(a) and (b) (21 CFR 570.35(a) and (b))). Because the GRAS review did not cover all GRAS substances (e.g., it did not cover many substances that were marketed based on a manufacturer’s independent GRAS determination), that rulemaking included a mechanism (the GRAS petition process currently codified in § 570.35(c)) whereby an individual could petition FDA to review the GRAS status of substances (37 FR 25705, December 2, 1972).

#### D. The 1997 Proposed Rule

In the **Federal Register** of April 17, 1997 (62 FR 18938) (the 1997 proposed rule), FDA published a proposed rule that would replace this voluntary GRAS affirmation petition process in §§ 170.35(c) (21 CFR 170.35(c)) and 570.35(c) with a voluntary notification procedure whereby any person may notify FDA of a determination that a particular use of a substance in human food (proposed § 170.36) or in animal food (proposed § 570.36) is GRAS.

FDA tentatively concluded in the 1997 proposed rule that the proposed notification procedure has advantages over the current petition process because the resource-intensive rulemaking that is associated with a petition would be eliminated. This streamlining would allow FDA to redirect its resources to questions about GRAS status that are a priority with respect to public health protection. In addition, the proposed notice is simpler than a GRAS affirmation petition and therefore conceivably would provide an incentive for manufacturers to inform FDA of their GRAS determinations. This would result in increased agency awareness of the composition of the nation’s food supply and the cumulative

dietary exposure to GRAS substances. FDA also tentatively concluded in the 1997 proposed rule that the public health would be better served if some resources that are currently directed to the GRAS petition process were redirected to the preparation of documents that would provide the industry with guidance on certain food safety issues for complex substances (e.g., macroingredients or biological polymers, such as proteins, carbohydrates, and fats and oils). Finally, FDA tentatively concluded that the reduction in resources devoted to the evaluation of GRAS substances would allow FDA to shift resources to its statutorily mandated task of reviewing food and color additive petitions (62 FR 18938 at 18941).

As part of the 1997 proposed rule, FDA announced an "interim policy" whereby interested persons could begin immediately to submit notifications of GRAS determinations (GRAS exemption claims) as described in proposed § 170.36(b) and (c) for substances used in human food. FDA stated that, in general, FDA would administer the notices as described in proposed § 170.36(d) through (f) (i.e., FDA would acknowledge receipt of the notice, respond in writing to the notifier, and make publicly accessible a copy of all GRAS determination claims and the agency's response). However, although FDA would make a good faith effort to respond within the proposed 90-day timeframe, the agency would not be bound by such a timeframe (62 FR 18938 at 18954).

As with the human food pilot program, the animal food pilot program, which will be administered by FDA's Center for Veterinary Medicine (CVM), will be based on the notification procedures announced in the 1997 proposed rule. Additionally, CVM has consulted with the Center for Food Safety and Applied Nutrition (CFSAN) and, where applicable, made its administrative procedures consistent with CFSAN's. Information about the CFSAN/GRAS notification program, including links to the 1997 proposed rule and relevant guidance documents, may be found at CFSAN's GRAS Web page: <http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/default.htm>.

## II. Description of the CVM Pilot Program

FDA is implementing a voluntary pilot program to accept submission of notices of claims that a particular use of a substance in food for animals is exempt from the statutory premarket approval requirements based on the

notifier's determination that such use is GRAS (notices of GRAS determination). FDA will accept notices of GRAS determination from all interested persons beginning immediately. However, FDA strongly encourages potential participants in the animal food pilot program to contact the Division of Animal Feeds (see **ADDRESSES**) prior to submitting notices to discuss their submission plans.

In general, the agency will implement the pilot program for substances added to animal food in the same manner as the interim policy for substances added to human food and as described in section VIII of the 1997 proposed rule (62 FR 18938 at 18954 through 18955). FDA invites interested persons who determine that a particular use of a substance in animal food is GRAS to notify FDA of such GRAS determination as described in section III of this document (see also proposed § 570.36(b) and (c) of the 1997 proposed rule.)

### III. How to Participate in the Pilot

Any person may notify FDA of a claim that a particular use of a substance is exempt from the statutory premarket approval requirements based on the notifier's determination that such use is GRAS. Notifiers should submit triplicate copies of their notices of GRAS determination to the Division of Animal Feeds (HFV-224), Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Notifiers should submit the following information:

- A claim, dated and signed by the notifier, or by the notifier's attorney or agent, or (if the notifier is a corporation) by an authorized official, that a particular use of a substance is exempt from the premarket approval requirements of the act because the notifier has determined that such use is GRAS. Such a claim should include:
  - The name and address of the notifier;
  - The common or usual name of the substance that is the subject of the GRAS determination claim (i.e., the "notified substance");
  - The applicable conditions of use of the notified substance, including the foods in which the substance is to be used, levels of use in such foods, and the purposes for which the substance is used, including, when appropriate, a description of the population (including the specific animal species) expected to consume the substance;
  - The basis for the GRAS determination (i.e., through scientific procedures or through experience based on common use in food); and

- A statement that the data and information that are the basis for the notifier's GRAS determination are available for FDA's review and copying at reasonable times at a specific address set out in the notice and will be sent to FDA upon request.

- Detailed information about the identity of the notified substance, including, as applicable, its chemical name, Chemical Abstracts Service (CAS) Registry Number, Enzyme Commission number, empirical formula, structural formula, quantitative composition, method of manufacture (excluding any trade secrets and including, for substances of natural biological origin, source information such as genus and species), characteristic properties, any content of potential human or animal toxicants, and specifications for feed-grade material;

- Information on any self-limiting levels of use; and
- A detailed summary of the basis for the notifier's determination that a particular use of the notified substance is exempt from the premarket approval requirements of the act because such use is GRAS. Such determination may be based either on scientific procedures or on common use in food.

- For a GRAS determination through scientific procedures, such summary should include:

- A comprehensive discussion of, and citations to, generally available and accepted scientific data, information, methods, or principles that the notifier relies on to establish safety, including a consideration of the probable consumption of the substance and the probable consumption of any substance formed in or on food because of its use and the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substances in such diet. Where a substance is intended for use in the food of an animal used to produce human food, this should include a comprehensive discussion of, and citations to, generally accepted scientific data, information, methods, or principles about both safety to the target animal and human food safety. The scientific data, information, methods, or principles provided should be sufficient to show that the substance is generally recognized among qualified experts to be safe for animals consuming food containing the substance as well as to humans consuming food derived from such animals (i.e., under its intended conditions of use);

- A comprehensive discussion of any reports of investigations or other information that may appear to be

inconsistent with the GRAS determination; and

—The basis for concluding, in light of the data and information submitted, that there is consensus among experts qualified by scientific training and experience to evaluate the safety of substances added to food that there is reasonable certainty that the substance is not harmful under the intended conditions of use.

○ For a GRAS determination through experience based on common use in food, such summary should include:

—A comprehensive discussion of, and citations to, generally available data and information that the notifier relies on to establish safety, including documented evidence of a substantial history of consumption of the substance by a significant number of animals. Where a substance is intended for use in the food of an animal used to produce human food, this should include a comprehensive discussion of, and citations to, generally accepted scientific data, information, methods, or principles about both safety to the target animal and human food safety. The scientific data, information, methods, or principles provided should be sufficient to show that the substance is generally recognized among qualified experts to be safe for animals consuming food containing the substance as well as to humans consuming food derived from such animals (i.e., under its intended conditions of use);

—A comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination;

—The basis for concluding, in light of the data and information submitted, that there is consensus among experts qualified by scientific training and experience to evaluate the safety of substances added to food that there is reasonable certainty that the substance is not harmful under the intended conditions of use.

#### IV. How FDA Will Administer Notices Under the Pilot Program

In general, the agency will administer the notices under the pilot program as described in proposed § 570.36(d) through (f) of the 1997 proposed rule, as follows:

1. Within 30 days of receipt of the notice, FDA intends to acknowledge receipt of the notice by informing the notifier in writing.

2. Under the 1997 proposed rule, FDA would respond to the notifier in writing within 90 days of receipt of the notice either that the notice provides a sufficient basis for the GRAS

determination or that FDA has identified questions as to whether the intended use of the substance is GRAS. Due to resource limitations in the animal food program, it is unlikely that CVM will be able to evaluate and respond to notices within the 90-day timeframe contained in the 1997 proposed rule. CVM will therefore respond to notifications of GRAS determinations in its pilot program as quickly as resources permit.

• Any GRAS determination claim submitted as part of the pilot program shall be immediately available for public disclosure on the date the notice is received. All remaining data and information in the notice shall be available for public disclosure, in accordance with 21 CFR part 20, on the date the notice is received.

• For each notice of GRAS determination submitted under the pilot program, the following information shall be readily accessible for public review and copying:

○ A copy of the submitted GRAS determination claim,

○ A copy of any letter issued by the agency, as described in paragraph 2 of this section.

○ A copy of any subsequent letter issued by the agency regarding such notice.

#### V. Paperwork Reduction Act of 1995

The collections of information in this notice are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), and have been previously approved by OMB. OMB originally approved Paperwork Reduction Act (PRA) burdens for GRAS notification under the 1997 proposed rule under OMB control number 0910–0342. The original OMB approval covered the collections of information in both proposed 21 CFR 170.36 and 570.36; however, only CFSAN operated a GRAS notification program for human food under the original OMB PRA approval. Extension of the original OMB PRA approval for GRAS notification was granted by OMB on August 24, 2009, under OMB control number 0910–0342.

As with the human food GRAS notification program administered by CFSAN, which has operated for several years, the animal food pilot program, which will be administered by CVM, will be based on the notification procedures announced in the 1997 proposed rule. The provisions for GRAS notification under proposed §§ 170.36 and 570.36 for human and animal food, respectively, are virtually identical and therefore the same number of hours per

response were estimated for reporting (150 hours) and recordkeeping (15 hours per record) burdens for both proposed sections under the original and extended OMB PRA approvals. Because CFSAN's GRAS program has successfully operated under these PRA estimates for several years, FDA believes these burden estimates remain accurate for CVM's GRAS pilot program.

FDA's estimate of the annual number of GRAS determination notices that will be received by CVM in the extended OMB PRA approval (5) was revised downward from the original PRA approval (10). This revision was based on the actual number of GRAS notices received by CFSAN from 1998 to 2008, which was lower than anticipated and caused CFSAN to also revise downward its estimate in the extended PRA approval. The revised estimate in the extended PRA approval reflects FDA's best judgment at this time as to the number of notices CVM will receive annually through this pilot program.

CVM believes that the PRA estimates in the extended PRA approval cover CVM's GRAS notice program.

Dated: May 26, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

#### Notice of Issuance of Final Determination Concerning a Lift Unit for an Overhead Patient Lift System

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security.

**ACTION:** Notice of final determination.

**SUMMARY:** This document provides notice that U.S. Customs and Border Protection (“CBP”) has issued a final determination concerning the country of origin of a lift unit for an overhead patient lift system. Based upon the facts presented, CBP has concluded in the final determination that Sweden is the country of origin of the lift unit for purposes of U.S. government procurement.

**DATES:** The final determination was issued on May 28, 2010. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination within July 6, 2010.