

Administration for Children and Families, Reports Clearance Officer, Roberta Katson at (202) 401-5756.

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503, (202) 395-7316.

Dated: April 10, 1996.

Roberta Katson,

*Director, Office of Information Resource Management Services.*

[FR Doc. 96-9750 Filed 4-19-96; 8:45 am]

BILLING CODE 4184-01-M

[Program Announcement No. ACF/ACYF/RHYP 96-2]

**Runaway and Homeless Youth Program (RHYP): Fiscal Year (FY) 1996 Final Program Priorities, Availability of Financial Assistance for Fiscal Year 1996, and Request for Applications for FY 1996 and FY 1997**

**AGENCY:** Family and Youth Services Bureau (FYSB), Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

**ACTION:** Extension of due date for receipt of applications for the Basic Center Program for Runaway and Homeless Youth (BCP) for FY 1996.

**SUMMARY:** This notice amends program announcement number ACF-ACYF-RHYP-96-2 published in the Federal Register on April 15, 1996 by extending the due date for submission of the BCP applications to June 7, 1996. This notice does not affect the due date for TLP applications. That date remains June 14, 1996.

**FOR FURTHER INFORMATION CONTACT:** Administration on Children, Youth and Families, Family and Youth Services Bureau, P.O. Box 1182, Washington, DC 20013; Telephone: 1-800-351-2293.

**SUPPLEMENTARY INFORMATION:** Under Part A of the Runaway and Homeless Youth Act, as amended, the overall purpose of the Basic Center Program is to provide financial assistance to establish or strengthen community-based centers that address the immediate needs (outreach, temporary shelter, food, clothing, counseling, aftercare, and related services) of runaway and homeless youth and their families.

(Catalog of Federal Domestic Assistance. Number 93.623, Basic Center Program for

Runaway and Homeless Youth; Number 93.550)

Dated: April 16, 1996.

Olivia A. Golden,

*Commissioner, Administration on Children, Youth and Families.*

[FR Doc. 96-9861 Filed 4-19-96; 8:45 am]

BILLING CODE 4184-01-M

**President's Committee on Mental Retardation; Notice of Meeting**

**AGENCY HOLDING THE MEETING:**

President's Committee on Mental Retardation.

**TIME AND DATE:** Full Committee Meeting, May 24, 1996, 10:00 a.m.-4:00 p.m.

**PLACE:** Hyatt Regency Washington on Capitol Hill, 400 New Jersey Avenue, NW., Washington, DC 20001.

**STATUS:** Meetings are open to the public. An interpreter for the deaf will be available upon advance request. All locations are barrier free.

**TO BE CONSIDERED:** The Committee plans to discuss critical issues concerning Federal Policy, Federal Research and Demonstration, State Policy Collaboration, Minority and Cultural Diversity and Mission and Public Awareness.

THE PCMR acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs and services for persons with mental retardation. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs for persons with mental retardation, and for reviewing legislative proposals that impact the quality of life that is experienced by citizens with mental retardation and their families.

**CONTACT PERSON FOR MORE INFORMATION:**

Gary H. Blumenthal, Wilbur J. Cohen Building, Room 5325, 330 Independence Avenue, SW., Washington, DC 20201-0001, (202) 619-0634.

Dated: April 16, 1996.

Gary H. Blumenthal,

*Executive Director, PCMR.*

[FR Doc. 96-9860 Filed 4-19-96; 8:45 am]

BILLING CODE 4184-01-M

**Food And Drug Administration**

[Docket No. 95N-0308]

**Inapplicability of the Dietary Supplement Health and Education Act to Animal Products**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is providing guidance regarding the inapplicability of the Dietary Supplement Health and Education Act of 1994 (the DSHEA) to products intended for use in animals. The agency is issuing this notice in response to inquiries received on whether the DSHEA applies to products intended for use in animals.

**DATES:** Submit written comments by July 22, 1996.

**ADDRESSES:** Written comments may be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

Comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:**

Donny Dean, Center for Veterinary Medicine (HFV-236), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1726.

**SUPPLEMENTARY INFORMATION:** FDA has had inquiries concerning whether the DSHEA applies to products intended for use in animals. After examining the statutory language, intent, and legislative history, the agency has determined that the DSHEA does not apply to animal products.

On October 25, 1994, the DSHEA (Pub. L. 103-417) was signed into law. The DSHEA amends the Federal Food, Drug, and Cosmetic Act (the act) to create a new regulatory scheme for "dietary supplements." The DSHEA, among other things, amended the act by adding section 201(ff) (21 U.S.C. 321(ff)), which defines a "dietary supplement," in part, as a product, other than tobacco, intended to supplement the diet that contains at least one or more of the following ingredients: A vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of any of the previously

mentioned ingredients (section 201(ff)(1) of the act). The DSHEA's main effect on the act was the removal of certain dietary supplement ingredients from regulation under 21 U.S.C. 321(s) and 348, two provisions of the act regulating the safety of food ingredients. In addition, the DSHEA permits certain limited claims to be made about dietary supplements without resulting in the supplement becoming a drug under 21 U.S.C. 321(g).

The definition of "dietary supplement" in the DSHEA does not explicitly state whether it includes or excludes products intended for use in animals other than man. The legislative record, which is extremely brief, is likewise silent about this issue. FDA has carefully examined the new law to determine if it should be applied to animal products, and believes that it should not. When the DSHEA is read as a whole, FDA believes it is evident that Congress was concerned only with human products and did not consider animal products. For this reason, the agency concludes that Congress did not intend the law to apply to animal products. Equally important, there are some critical differences between products intended for human use and products intended for animal use that strongly favor maintaining the status quo for animal products. Accordingly, FDA does not intend to apply the DSHEA to animal products.

There is much evidence in the DSHEA that Congress did not intend to apply the amendments to animal products. First, the extensive congressional findings in section 2 of the DSHEA focus strictly on the use of dietary supplements by humans. These findings begin by stating that "improving the health status of United States citizens ranks at the top of the national priorities \* \* \*," *id.*, section 2(l) of the DSHEA (emphasis added); see also *id.*, section 2(3)(A) and 2(4) of the DSHEA (discussing the effect of supplements on human health conditions, such as "cancer, heart disease, and osteoporosis" and "medical procedures, such as coronary bypass surgery or angioplasty.") This strict focus on humans in the congressional findings reflects Congress' intent that the law apply only to humans. See *United States v. Solid Gold Holistic Animal Equine Nutrition Center et al.*, No. CV 88-0473-GT, slip op. at 7-8 (S.D. Cal. March 2, 1995) (Ref. 1).

Next, although the definition of "dietary supplement" contains no explicit reference to products intended for use by animals, part of the definition does contain an explicit reference to products intended for use by humans

(section 3 of the DSHEA (creating 21 U.S.C. 321(ff)(1)(E))). This is further evidence that Congress intended the law to apply to supplements used by humans, not supplements for other animals.

Furthermore, many of the changes made by the DSHEA apply only to supplements intended for human use because the sections of the act that were amended by the DSHEA apply only to human products—yet another strong signal that Congress was only concerned with human supplements. For example, when the DSHEA sets out the standards for determining whether a product that has been approved or investigated as a drug can also be sold as a dietary supplement, it cites only to the human drug provisions of the act, but not to any of the animal drug provisions. See 21 U.S.C. 321(ff)(3). Likewise, the changes to food labeling made by the DSHEA apply only to human food because the sections in the act that are amended are in 21 U.S.C. 343(r), which applies only to "food for human consumption."

Moreover, FDA believes the public health will be better protected if ingredients in animal dietary supplements are not subject to the special treatment provided for ingredients of human supplements by the DSHEA. Under the act's food additive provisions, 21 U.S.C. 321(s) and 348, before FDA can approve a product for use in a food producing animal, FDA must determine that the product will not leave harmful residues in food (21 U.S.C. 348(b)(2) and (c)(5), and 21 CFR part 570). If the compound or any of its metabolites induces cancer, the act imposes additional requirements on the approval of the compound (21 U.S.C. 348(c)(3)(A) and 21 CFR part 500, subpart E). However, nowhere in its revision of the regulation of ingredients in dietary supplements does the DSHEA address how the effect of supplements on food producing animals and human food safety is to be assessed. It seems unlikely that Congress would so alter the regulation of animal foods with no consideration—indeed, no mention—of the impact of the alteration on the safety of the nation's food supply.<sup>1</sup>

Not only are there human food safety concerns, but when compared with human use of supplements, there is less information on the safe use of dietary supplements in animals. Many

<sup>1</sup>The findings make clear that one underpinning of the new legislation was Congressional concern that consumers should have the freedom to make their own choices about whether to take dietary supplements. However, that critical element of consumer choice is lacking when the supplement (or its metabolite) ends up in the diet as an unidentified residue in meat, milk, or eggs.

substances that fall under the definition of dietary supplements for human consumption, such as herbs and other botanicals, have a history of use in humans that can be used to establish reasonably safe levels. However, the same is not true for use of many of these same ingredients in animals. As far as FDA is aware, very few substances that meet the criteria of 21 U.S.C. 321(ff)(1) and (ff)(2) have any established history of safe use in any animal. Moreover, each animal species requires different nutrients, absorbs and metabolizes nutrients differently, and can exhibit different toxic reactions to food and its components. The lack of information on the safe use of these kinds of substances in animals, and the fact that the animal population is not as homogenous as the human population are two more reasons why FDA has determined that the DSHEA should not apply to animal products.<sup>2</sup>

Finally, many drugs intended to increase the production of meat, milk, egg, or fiber (so-called production drugs) or otherwise affect animal performance could arguably be covered as dietary supplements under the DSHEA. Currently, products bearing such production claims are animal drugs under the act, and as such, can only be marketed after approval by FDA after the manufacturer conducts extensive scientific studies to show that the drug is both safe (in animals and humans) and effective (21 U.S.C. 360b). To allow new production drugs to be marketed under the provisions of the DSHEA not only raises exactly the same food safety concerns previously discussed about food additives, but would also be unfair to existing approved products, and would serve as a disincentive to develop and use legitimate drugs in the future.

In sum, although the DSHEA does not speak directly to the question, we think that the DSHEA was not intended to apply to animal products. Moreover, we

<sup>2</sup>The law devotes no resources to the human and animal health issues raised by the use of supplements in animals. The DSHEA does mandate the establishment of an office within the National Institutes of Health to oversee scientific study of dietary supplements, as well as a seven-member commission to provide recommendations for the regulation of label claims for supplements. However, nothing in the law directs either new group to address the use of dietary supplements in animals. Thus, there will not be any independent resource from which the Center for Veterinary Medicine (CVM) can obtain unbiased information on benefits to animal health and production, safety to animals and humans consuming edible byproducts from treated animals, or the validity of claims for animal supplements. Lacking such a resource, FDA believes it is prudent for the burden to remain, as it is now, on the manufacturer to generate safety and effectiveness data and provide it to FDA for review in feed additive petitions and new animal drug applications.

believe that there are significant, complex scientific and regulatory issues relating to human and animal safety that would need to be resolved by Congress before a similar scheme for animal supplements could be put into place. Accordingly, FDA has concluded that animal dietary supplements are not covered by the DSHEA.

Interested persons may, on or before July 22, 1996, submit to the Dockets Management Branch (address above) written comments on this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 11, 1996.

William B. Schultz,

*Deputy Commissioner for Policy.*

[FR Doc. 96-9780 Filed 4-19-96; 8:45 am]

BILLING CODE 4160-01-F

## Food and Drug Administration

[Docket No. 84N-0102]

### Cumulative List of Orphan Drug and Biological Designations

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a cumulative list of designated orphan drugs and biologics as of December 31, 1995. FDA has announced the availability of previous lists, which are brought up-to-date monthly, identifying the drugs and biologics granted orphan-drug designation pursuant to the Federal Food, Drug, and Cosmetic Act (the act).

**ADDRESSES:** Copies of the list of current orphan-drug designations and of any future lists are or will be available from the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, and the Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3666.

**FOR FURTHER INFORMATION CONTACT:** Peter Vaccari, Office of Orphan Products Development (HF-35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-0983.

**SUPPLEMENTARY INFORMATION:** FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan-drug designation under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act, which requires public notification of designations, FDA maintains a list of designated orphan drugs and biologics. This list is made current on a monthly basis and is available upon request from OPD (contact identified above). At the end of each calendar year, the agency publishes an up-to-date cumulative list of designated orphan drugs and biologics, including the names of designated compounds, the specific disease or condition for which the compounds are designated, and the sponsors' names and addresses. The cumulative list of compounds receiving orphan-drug designation through 1988 was published in the Federal Register of April 21, 1989 (54 FR 16294). This list is available on request from FDA's Dockets Management Branch (address above). Those requesting a copy should specify the docket number found in brackets in the heading of this document.

The list that is the subject of this notice consists of designated orphan drugs and biologics through December 31, 1995, and, therefore, brings the March 2, 1993 (58 FR 12041), publication up-to-date.

The orphan-drug designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing an orphan drug or biological must apply for orphan-drug designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which designation is requested. (See 53 FR 47577, November 23, 1988.) Copies of the regulations (see 57 FR 62076, December 29, 1992) for use in preparing an application for orphan-drug designation may be obtained from OPD (address above).

The names used in the cumulative list for the drug and biological products that have not been approved or licensed for marketing may not be the established or proper names approved by FDA for these products if they are eventually approved or licensed for marketing. Because these products are investigational, some may not have been reviewed for purposes of assigning the most appropriate established proper name.

Dated: April 11, 1996.

William K. Hubbard,

*Associate Commissioner for Policy Coordination.*

[FR Doc. 96-9782 Filed 4-19-96; 8:45 am]

BILLING CODE 4160-01-F

### Advisory Committees; Tentative Schedule of Meetings for 1996

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for the remainder of 1996. At the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. The IOM recommended that the agency publish an annual tentative schedule of its meetings in the Federal Register. In response to that recommendation, FDA is publishing its annual tentative schedule of meetings for the remainder of 1996.

#### FOR FURTHER INFORMATION CONTACT:

Donna M. Combs, Committee Management Office (HFA-306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2765.

**SUPPLEMENTARY INFORMATION:** The IOM, at the request of the Commissioner, undertook a study of the use of FDA's advisory committees. In its final report, the IOM recommended that FDA adopt a policy of publishing an advance yearly schedule of its upcoming public advisory committee meetings in the Federal Register. FDA has implemented this recommendation. A tentative schedule of forthcoming meetings will be published annually in the Federal Register. The annual publication of tentatively scheduled advisory committee meetings will provide both advisory committee members and the public with the opportunity, in advance, to schedule attendance at FDA's upcoming advisory committee meetings. The schedule is tentative and amendments to this notice will not be published in the Federal Register. FDA will, however, publish a Federal Register notice 15 days in advance of each upcoming advisory committee meeting, announcing the meeting (21 CFR 14.20).

The following list announces FDA's tentatively scheduled advisory committee meetings for the remainder of 1996: