New Animal Drug Application (NADA), Form FDA 356 V—21 CFR Part 514—(OMB Control No. 0910–0032)—Extension

FDA has the responsibility under the Federal Food, Drug, and Cosmetic Act (the act), for the approval of new animal drugs that are safe and effective. Section 512(b) of the act (21 U.S.C. 360b(b)), requires that a sponsor submit and receive approval of a NADA, before interstate marketing is allowed. The regulations implementing statutory requirements for NADA approval have been codified under 21 CFR part 514. NADA applicants generally use a single form, FDA 356 V. The NADA must contain, among other things, safety and effectiveness data for the drug, labeling, a list of components, manufacturing and controls information, and complete information on any methods used to determine residues of drug chemicals in edible tissues. While the NADA is pending, an amended application may be submitted for proposed changes. After an NADA has been approved, a supplemental application must be submitted for certain proposed changes, including changes beyond the variations provided for in the NADA and other labeling changes. An amended application and a supplemental application may omit statements concerning which no change is proposed. This information is reviewed by FDA's scientific personnel to ensure that the intended use of an animal drug, whether as a pharmaceutical dosage form, in drinking water, or in medicated feed, is safe and effective. The respondents are pharmaceutical firms that produce veterinary products and commercial feed mills.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No.	21 CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Form FDA 356 V	514.1 and 514.6	190	8.33	1,582	211.6	334,751
	514.8	190	8.33	1,582	30	47,460
	514.11	190	8.33	1,582	1	1,582
Total						383,793

[1] There are no capital costs or operating and maintenance costs associated with this collection.

The estimate of the burden hours required for reporting are based on fiscal year 1999 data. The burden estimate includes original NADA's, supplemental NADA's, and amendments to unapproved applications.

Dated: January 16, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–1870 Filed 1–22–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01F–0026]

Avecia, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Avecia, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of Poly(hexamethylenebiguanide) hydrochloride as a preservative for food-contact paper coating formulations.

FOR FURTHER INFORMATION CONTACT: Mark Hepp, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3098.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 1B4726) has been filed by Avecia, Inc., 1405 Foulk Rd., P.O. Box 15457, Wilmington, DE 19850–5457. The petition proposes to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) and § 176.180 *Components of paper and paperboard in contact with dry food* (21 CFR 176.180) to provide for the safe use of Poly(hexamethylenebiguanide) hydrochloride as a preservative for food-contact paper coating compositions.

The agency has determined under 21 CFR 25.32(q) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: January 4, 2001.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 01–1868 Filed 1–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration (SAMHSA)

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the Center for Mental Health Services (CMHS) National Advisory Council on January 25 and 26, 2001.

A portion of the meeting will be open and will include a roll call, general announcements and panel discussions on racial and ethnic disparities in mental health, the role of communications in promoting mental health for children, communication efforts in promoting appropriate messages about mental illness. There will be an update from the subcommitte on consumer/survivor issues and a report of the Surgeon General's conference on children's mental health. Public comments are welcome during the open session. Please communicate with the individual listed as contact below for guidance.

The meeting will include the review, discussion, and evaluation of individual grant applications. Therefore a portion of the meeting will be closed to the public as determined by the Acting Administrator, SAMHSA, in accordance with title 5 U.S.C. 552b (c)(6) and 5 U.S.C. App. 2, section 10(d).

A summary of the meeting and a roster of Council members may be obtained from: Ms. Eileen Pensinger, M.Ed., Executive Secretary, CMHS National Advisory Council, 5600 Fishers Lane, Room 17C–27, Rockville, Maryland 20857, Telephone: (301) 443–4823.

Substantive program information may be obtained from the contact whose name and telephone number is listed below.

Committee Name: Center for Mental Health Services, National Advisory Council.

Meeting Date: January 25 and 26, 2001.

Place: Parklawn Building, 5600 Fishers Lane, Conference Room D, 3rd Floor, Rockville, Maryland 20857.

Closed: January 25, 2001, 9 a.m, to 10 a.m.

Open: January 25, 2001, 10:15 a.m. to 5 p.m.; January 26, 2001, 8:30 a.m. to 1 p.m.

Contact: Eileen Pensinger, M.Ed., Parklawn Building, 5600 Fishers Lane, Room 17C–27, Telephone: (301) 443–4823 and FAX: (301) 443–4864.

Dated: January 16, 2001.

Toian Vaughn,

Committee Management Officer, SAMHSA.

[FR Doc. 01–1871 Filed 1–22–01; 8:45 am]

BILLING CODE 4162–20–U

DEPARTMENT OF THE INTERIOR

Office of the Secretary; Glen Canyon Dam Adaptive Management Work Group; Notice of Renewal

This notice is published in accordance with section 9(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463). Following consultation with the General Services Administration, notice is hereby given that the Secretary of the Interior (Secretary) is renewing the Glen Canyon Dam Adaptive Management Work Group. The purpose of the Adaptive Management Work Group is to advise and provide recommendations to the Secretary with respect to his responsibility to comply with the Grand Canyon Protection Act of October 30, 1992, embodied in Public Law 102–575.

Further information regarding the advisory council may be obtained from the Bureau of Reclamation, Department of the Interior, 1849 C Street, NW, Washington, DC 20240.

The certification of renewal is published below.

Certification

I hereby certify that establishment of the Glen Canyon Dam Adaptive Management Work Group is in the public interest in connection with the purpose of duties imposed on the Department of the Interior by 30 U.S.C. 1–8.

Dated: January 16, 2001.

Bruce Babbitt,

Secretary of the Interior.

[FR Doc. 01–1872 Filed 1–22–01; 8:45 am]

BILLING CODE 4310–MN–M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

List of Programs Eligible for Inclusion in Fiscal Year 2002 Annual Funding Agreements To Be Negotiated With Self-Governance Tribes by Interior Bureaus Other Than the Bureau of Indian Affairs

AGENCY: Office of the Secretary, Interior.

ACTION: Notice.

SUMMARY: This notice lists programs or portions of programs that are eligible for inclusion in Fiscal Year 2002 annual funding agreements with self-governance tribes and lists programmatic targets for each of the non-BIA bureaus, pursuant to section 405(c)(4) of the Tribal Self-Governance Act.

DATES: This notice expires on September 30, 2002.

ADDRESSES: Inquiries or comments regarding this notice may be directed to the Office of Self-Governance (MS–2542, MIB), 1849 C Street NW., Washington, DC 20240–0001. Telephone (202) 219–0240 or to the bureau points of contact listed below.

SUPPLEMENTARY INFORMATION:

I. Background

Title II of the Indian Self-Determination and Education Assistance Act Amendments of 1994 (Pub. L. 103–413, the ''Self-Governance Act'' or the ''Act'') instituted a permanent tribal self-governance program at the Department of the Interior (DOI). Under the self-governance program certain programs, services, functions, and activities, or portions thereof, in Interior bureaus other than BIA are eligible to be planned, conducted, consolidated, and administered by a self-governance tribal government.

Under section 405(c) of the Self-Governance Act, the Secretary of the Interior is required to publish annually: (1) A list of non-BIA programs, services, functions, and activities, or portions thereof, that are eligible for inclusion in agreements negotiated under the self-governance program; and (2) programmatic targets for these bureaus.

Under the Self-Governance Act, two categories of non-BIA programs are eligible for self-governance funding agreements:

(1) Under section 403(b)(2) of the Act, any non-BIA program, service, function or activity that is administered by Interior that is ''otherwise available to Indian tribes or Indians,'' can be administered by a tribal government through a self-governance agreement. The Department interprets this provision to authorize the inclusion of programs eligible for self-determination contracting under Title I of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638). Section 403(b)(2) also specifies that ''nothing in this subsection may be construed to provide any tribe with a preference with respect to the opportunity of the tribe to administer programs, services, functions and activities, or portions thereof, unless such preference is otherwise provided for by law.''

(2) Under section 403(c) of the Act, the Secretary may include other programs, services, functions, and activities, or portions thereof, that are of ''special geographic, historical, or cultural significance'' to a self-governance tribe.

Under section 403(k) of the Self-Governance Act, annual agreements cannot include programs, services, functions, or activities that are inherently Federal or where the statute establishing the existing program does not authorize the type of participation sought by the tribe. However, a tribe (or tribes) need not be identified in the authorizing statutes in order for a program or element to be included in a self-governance agreement. While general legal and policy guidance regarding what constitutes an inherently Federal function exists, we will determine whether a specific function is inherently Federal on a case-by-case basis considering the totality of circumstances.

Response to Comments

The Department provided the proposed list to the Self-Governance Tribes at the semi-annual Tribal Self-Governance Fall Conference held in Nashville, Tennessee on October 10–12, 2000. No comments were received. Several minor editorial and technical change provided by Interior's bureaus were incorporated.

II. Annual Funding Agreements Between Self-Governance Tribes and Non-BIA Bureaus of the Department of the Interior

A. Bureau of Land Management (none)

B. Bureau of Reclamation (3)