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).