animals and etiologic agents in order to protect the public health. Currently, with the exception of rodent inspections and the cruise ship sanitation program, inspections are performed only on those vessels and aircraft which report illness prior to arrival or when illness is discovered upon arrival. Other inspection agencies assist quarantine officers in public health screening of persons, pets, and other importations of public health importance and make referrals to PHS when indicated. These practices and procedures assure protection against the introduction and spread of communicable diseases into the United States with a minimum of recordkeeping and reporting as well as a minimum of interference with trade and travel. Respondents would include airplane pilots, ships' captains, importers, and travelers. The nature of the quarantine response would dictate which forms are completed by whom. Thus, the *respondents* portion of the information below is replaced by the requisite form title. The estimated cost to the public is $22,225.

Respondents	Number of respondents	Number of responses/ respondent	Avg. burden per respondent (in hrs.)	Total burden (in hrs.)
Radio reporting of death/illness:				
(1) Aircraft	130	1	2/60	4.00
(2) Cruise ships	90	23	1/60	34.00
(3) Other ships	22	1	1/60	0.04
Report by persons held in isolation/surveillance	11	1	30/60	5.50
Report of death or illness on carrier during stay in port	5	1	3/60	0.25
Requirements for admission of dogs and cats:				
(1)	5	1	3/60	0.25
(2)	2,650	1	15/60	662.50
Application for permits to import turtles	10	1	30/60	5.00
Requirements for registered importers of nonhuman primates:				
(1)	40	1	10/60	6.70
(2)	50	1	30/60	25.00
Total				743.60

Dated: January 12, 2001.

Nancy Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–1996 Filed 1–22–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0006]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drug Application, Form FDA 356 V, 21 CFR Part 514

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for submission of a new animal drug application (NADA).

DATES: Submit written or electronic comments on the collection of information by March 26, 2001.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at: http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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).