TABLE 1.—Estimated Annual Reporting Burden[1]—Continued

21 CFR Section/Form	No. of Respondents	No. of Responses per Respondents	Total Annual Responses	Hours per Response	Total Hours
314.98(c) (FDA 2252)	265	17.17	4,551	40	182,040
314.99(a)	46	13.04	600	2	1,200
314.110(a)(5)	55	1.13	62	8	496
314.120(a)(5)	26	1.12	29	8	232
314.420	450	1.11	500	8	4,000
Total Burden Hours					2,158,470

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

Dated: May 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–14050 Filed 5–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0273]

Texas Vitamin Co., RSR Laboratories Inc.; Proposal to Withdraw Approval of New Animal Drug Applications; Opportunity for Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing an opportunity for hearing on a proposal to withdraw approval of new animal drug application (NADA) 117–688 held by Texas Vitamin Co. and NADA 140–850 held by RSR Laboratories Inc., because the applicants have failed to submit required periodic reports. FDA has been unable to locate the firms and to contact them at their previous business addresses.

DATES: Requests for hearing with data, analysis, and information relied upon to justify a request for hearing are due by June 29, 1998.

ADDRESSES: Requests for hearing filed in response to this notice should be identified with Docket No. 98N–0273 and sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Glenn A. Peterson, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0224; or

Mukund R. Parkhie, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6642.

SUPPLEMENTARY INFORMATION: An applicant is required to report periodically to the Center for Veterinary Medicine (CVM) concerning each applicant's approved NADA as provided in § 510.300 (21 CFR 510.300). Texas Vitamin Co., P.O. Box 18417, 10695 Aledo St., Dallas, TX 57218 (last known address), is sponsor of NADA 117–688. RSR Laboratories Inc., 501 Fifth St., Bristol, TN 37620 (last known address), is sponsor of NADA 140–850. The sponsors have not submitted the required periodic reports for their NADA's and have not responded to CVM requests for submission of those reports. Letters to the firms have been returned indicating the firms are no longer at the above-listed addresses.

Therefore, notice is given to Texas Vitamin Co. and RSR Laboratories Inc., and to all other interested persons who may be adversely affected, that the Director, CVM, proposes to issue an order under section 512(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(e)) withdrawing approval of NADA's 117–688 and 140–850 and all amendments and supplements thereto on the ground that the applicants have failed to submit the reports required under § 510.300. Upon withdrawal of the NADA's, the applicable parts of the regulations in 21 CFR 510.600(c)(1) and (c)(2) and 520.580(b)(1) will be revoked.

In accordance with the provisions of section 512 of the act and regulations issued under it (parts 510 and 514 (21 CFR parts 510 and 514)), and under authority delegated to the Director, CVM (§ 5.84 (21 CFR 5.84)), CVM hereby provides the applicants an opportunity for hearing to show why approval of the NADA's and all amendments and supplements thereto should not be withdrawn (and the corresponding regulations revoked) and an opportunity to raise, for administrative determination, all issues relating to the legal status of the application and drug products approved thereunder. Any hearing would be subject to the provisions of 21 CFR part 12.

An applicant who decides to seek a hearing shall file on or before June 29, 1998, a written notice of appearance, request for hearing, and data, information, and analyses relied on to justify a hearing as specified in § 514.200.

Procedures and requirements governing this notice of opportunity for hearing, notice of appearance and request for hearing, submission of information and analysis to justify a hearing, other comments, and a grant or denial of a hearing, are contained in § 514.200.

The failure of an applicant to file a timely, written notice of appearance and request for hearing as required by § 514.200 constitutes an election by the applicant not to make use of the opportunity for hearing concerning the proposed action and constitutes a waiver of any contentions about the legal status of the product. In such case, the Director, CVM, under the authority delegated to him in § 5.84(a)(2), will, without further notice, enter a final order withdrawing approval of the application. Thereafter, the product may not be legally marketed, and FDA may begin appropriate regulatory action to remove it from the market. Any new animal drug product that is not the subject of an approved application is subject to regulatory action at any time.

A request for hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that justifies a hearing. Reports submitted to remedy the deficiencies must be complete in all respects as required by § 510.300. If the reports submitted are not complete or there is no genuine and substantial issue of fact that precludes the withdrawal of approval, or the request for hearing is not made in the required format or with the required analysis, the Commissioner of Food and Drugs will enter summary judgment against the person who

requests the hearing, making findings and conclusions, and denying a hearing. If a hearing is requested and is justified by the sponsor's response to this notice, the issues will be defined, an administrative law judge will be assigned, and a written notice of the time and place at which the hearing will begin will be issued.

All submissions under this notice shall be filed in two copies. Except for information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 512(e) (21 U.S.C. 360b(e))) and under authority delegated to the Director, Center For Veterinary Medicine (21 CFR 5.84).

Dated: May 20, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–14103 Filed 5–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Joint Meeting of the Pulmonary-Allergy Drugs and Endocrinologic and Metabolic Drugs Advisory Committees; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Joint meeting of the Pulmonary-Allergy Drugs and the Endocrinologic and Metabolic Drugs Advisory Committees.

General Function of the Committees: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on July 30, 1998, 8 a.m. to 5 p.m., and on July 31, 1998, 8 a.m. to 3:45 p.m.

Location: Bethesda Marriott Hotel, Grand Ballroom, 5151 Pooks Hill Rd., Bethesda, MD.

Contact Person: Leander B. Madoo or Kathleen R. Reedy, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), codes 12545 and 12536. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 30, 1998, the committees will: (1) Discuss the impact of orally inhaled and intranasal corticosteroids on growth in children, (2) hear from invited experts regarding the process of normal growth and development in children and how various factors including corticosteroids may impact on it, and (3) review examples from industry of completed ''growth studies'' testing the various inhaled and intranasal corticosteroid drug products. On July 31, 1998, the agency will: (1) Present the proposed ''class labeling'' for inhaled and intranasal corticosteroid drug products, (2) review the data which support it, and (3) lead a general scientific discussion among all meeting participants to reach a consensus concerning appropriate labeling for these products and recommendations for the design and conduct of future clinical trials which assess growth.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 23, 1998. Oral presentations from the public will be scheduled between approximately 3 p.m. and 4:30 p.m., on July 30, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 23, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 20, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–14106 Filed 5–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Healthy Start Initiative—Phase II Limited Competition for the Mississippi Delta

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of availability of funds for a limited competition for the ten counties of Mississippi known as the Mississippi Delta.

SUMMARY: The HRSA announces the availability funds in fiscal year 1998 for a single cooperative agreement for the replication of the Healthy Start Initiative (HSI) Phase II within the ten counties of Mississippi known as the Mississippi Delta. The Healthy Start Initiative is a program of projects which, since FY 1991, has developed and implemented community-based strategies to reduce infant mortality in areas with a high incidence of infant mortality. The purpose of Healthy Start-Phase II is to operationalize successful infant mortality reduction strategies developed during the demonstration phase and to launch Healthy Start projects in new rural and urban communities (i.e., communities currently without a Healthy Start Initiative-funded project). Within the HRSA, the Healthy Start Initiative is administered by the Maternal and Child Health Bureau (MCHB). This cooperative agreement for Healthy Start-Phase II in the Mississippi Delta will be made under the program authority of Section 301 of the Public Health Service Act. Funds for this award were appropriated under Public Law 104–208.

To continue Healthy Start efforts to meet critical maternal and child health needs in the Mississippi Delta, public and nonprofit private organizations serving the following counties in the Mississippi Delta—Humphries, Holmes, Leflore, Bolivar, Quitman, Sunflower, Tallahatchie, Washington, Cohoma, and Tunica—are encouraged to apply. Applicants must provide services to all ten counties. Only one applicant organization will be funded.

The project period is three years, subject to continuing availability of funds.

ADDRESSES: Interested parties may contact the HRSA Grants Application Center for an application package. Requests should specify the Healthy Start Initiative—Phase II limited competition within the Mississippi Delta (CFDA #93.926b). The Center may