interested in funding ''wish lists'' of business possibilities. ANA expects written evidence of the solid investment of time and consideration on the part of the applicant with regard to the development of business plans. Business plans should be developed based on market analysis and feasibility studies regarding the potential success to the business prior to the submission of the application.

- Core administration functions, or other activities, which essentially support only the applicant's on-going administrative functions.
- Project goals which are not responsive to one or more of the funding competitive areas.
- Projects that will not be completed, self-sustaining, or supported by other than ANA funds, at the end of the project period.
- Project goals which are not responsive to one or more of the funding competitive areas.
- Projects that will not be completed, self-sustaining, or supported by other than ANA funds, at the end of the project period.
- ANA will not fund investment capital for purchase or takeover of an existing business, for purchase or acquisition of a franchise, or for purchase of stock or other similar investment instruments.
- Renovation or alteration unless it is essential for the project. Renovation or alteration costs may not exceed the lesser of $150,000 or 25 percent of the total direct costs approved for the entire budget period.
- Projects originated and designed by consultants who provide a major role for themselves in the proposed project and are not members of the applicant organization.

I. Paperwork Reduction Act of 1995 (Pub. L. 104–13)

Public reporting burden for this collection of information is estimated to average 29.5 hours per response, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection of information.

The following information collections are included in the program announcement: ANA grant applications, OMB control number 0980–0204, expires August 31, 1999.

An agency may conduct or sponsor, and a person is not required to respond to, collection of information unless it displays a currently valid OMB control number.

J. Receipt of Applications

Applications must either be hand delivered or mailed to the address in Section F, The Application Process: Application Submission. The Administration for Native Americans cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ANA electronically will not be accepted regrdless of date or time of submission and time of receipt. Videotapes and cassette tapes may not be included as part of a grant application for panel review.

Applications and related materials postmarked after the closing date will be classified as late; and not considered in the current competition.

1. Deadlines

- Mailed applications shall be considered as meeting an announced deadline if they are either received on or before the deadline date or sent on or before the deadline date and received by ACF in time for the independent review to: U.S. Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Mail Stop 6C–462, Washington, D.C. 20447.
- Applicants are cautioned to request a legibly dated U.S. Postal Service postmark or to obtain a legibly dated receipt from a, commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- Applications hand carried by applicants, applicant couriers, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date or postmarked on or before the deadline date, Monday through Friday (excluding Federal holidays), between the hours of 8:00 am and 4:30 pm at: U.S. Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, ACF Mailroom, 2nd Floor Loading Dock, Aerospace Center, 901 D Street, SW., Washington, DC 20024. (Applicants are cautioned that express/overnight mail services do not always deliver as agreed.)
- ACF cannot accommodate transmission of applications by fax or through other electronic media. Therefore, applications transmitted to ACF electronically will not be accepted regardless of date or time of submission and time of receipt.
- No additional material will be accepted, or added to an application, unless it is postmarked by the deadline date.

2. Late Applications

Applications which do not meet the criteria above are considered late applications. ACF shall notify each late applicant that its application will not be considered in the current competition.

3. Extension of Deadlines

The Administration for Children and Families may extend an application deadline for applicants affected by acts of God such as floods and hurricanes, or when there is a widespread disruption of the mails. A determination to extend or waive deadline requirements rests with the Chief Grants Management Officer.

(Catalog of Federal Domestic Assistance Program Numbers: 93:612 Native American Programs)

Dated: May 22, 1998.

Gary N. Kimple,

Commissioner, Administration for Native Americans.

[FR Doc. 98–14132 Filed 5–27–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0304]

Agency Information Collection Activities: Proposed Collection; Comment Request

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 governing applications for FDA approval to market a new drug.

DATES: Submit written comments on the collection of information by July 27, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration,

12420 Parklawn Dr., rm. 1–23, 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: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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 set forth in this document.

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.

Applications for FDA Approval to Market a New Drug—21 CFR Part 314—(OMB Control Number 0910–0001)—Reinstatement

Under section 505(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(a)), a new drug may not be commercially marketed in the United States, imported, or exported from the United States, unless an approval of an application filed with FDA under section 505(b) or (j) of the act is effective with respect to such drug. Section 505(b) and (j) of the act requires a sponsor to submit to FDA a new drug application (NDA) containing, among other things, full reports of investigations that show whether or not the drug is safe and effective for use, a full list of articles used as components in the drug, a full description of manufacturing methods, samples of the drugs required, specimens of the labeling proposed to be used, and certain patent information as applicable. Under the act, it is the sponsor's responsibility to provide the information needed by FDA to make a scientific and technical determination that the product is safe and effective.

This information collection approval request is for all information requirements imposed on sponsors by the regulations under part 314 (21 CFR part 314) , who apply for approval of a NDA in order to market or to continue to market a drug.

The following sections in part 314 set forth the specific format and content requirements for NDA's.

Section 314.50(a) requires that an application form (Form FDA 356h) must be submitted that includes basic introductory information about the drug as well as a checklist of enclosures. (Section 314.50(a) is already approved by OMB under 0910–0338 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(b) requires that an index must be submitted with the archival copy of the application and that it must reference certain sections of the application.

Section 314.50(c) requires that a summary of the application must be submitted that presents a good general synopsis of all the technical sections and other information in the application.

Section 314.50(d) requires that the NDA contain the following technical sections about the new drug: Chemistry, manufacturing, and controls; nonclinical pharmacology and toxicology; human pharmacokinetics and bioavailability; microbiology; clinical data; and statistical section.

Section 314.50(e) requires that the applicant must submit samples of the drug if requested by FDA. In addition, the archival copy of the application must include copies of the label and all labeling for the drug.

Section 314.50(f) requires that case report forms and tabulations must be submitted with the archival copy.

Section 314.50(h) requires that patent information as described under § 314.53 must be submitted with the application. (Section 314.50(h) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(i) requires that a patent certification information must be submitted in 505(b)(2) applications for patents claiming the drug, drug product, method of use, or method of manufacturing. (Section 314.50(i) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(j) requires that applicants that request a period of marketing exclusivity must submit certain information with the application. (Section 314.50(j) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.50(k) requires that an archival, review, and field copy of the application must be submitted.

Section 314.52 requires that notice of certification of invalidity or noninfringement of a patent to patent holders and NDA holders must be sent by 505(b)(2) applicants and must follow certain content and notification procedures. (Section 314.52 is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.54 sets forth the content requirements for applications filed under section 505(b)(2) of the act.

Section 314.60 sets forth reporting requirements for sponsors who amend an unapproved application.

Section 314.65 states that the sponsor must notify FDA when withdrawing an unapproved application.

Sections 314.70 and 314.71 require that supplements must be submitted to FDA for certain changes to an approved application.

Section 314.72 requires sponsors to report to FDA any transfer of ownership of an application.

Section 314.80(c)(1) and (c)(2) sets forth requirements for expedited adverse drug experience postmarketing reports and followup reports, as well as for periodic adverse drug experience postmarketing reports (Form FDA 3500A). (Section 314.80(c)(1) and (c)(2) is already approved by OMB under 0910–0230 and 0910–0291 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.80(c)(1)(iii) and (i) establishes recordkeeping requirements for reports of postmarketing adverse drug experiences. (Section 314.80(c)(1)(iii) and (i) is already approved by OMB under 0910–0230 and 0910–0291 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.81(b)(1) requires that field alert reports must be submitted to FDA (Form FDA 3331).

Section 314.81(b)(2) requires that annual reports must be submitted to FDA (Form FDA 2252).

Section 314.81(b)(3)(i) requires that drug advertisements and promotional labeling must be submitted to FDA (Form FDA 2253). (Section 314.81(b)(3)(i) is already approved by OMB in ''Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use,'' which published in the **Federal Register** of October 24, 1997 (62 FR 55408), and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.81(b)(3)(iii) sets forth reporting requirements for sponsors who withdraw an approved drug product from sale. (Section 314.81(b)(3)(iii) is already approved by OMB under 0910–0045 and is not included in the hour burden estimates in Table 1 of this document).

Section 314.90 sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.50 through 314.81. (The information collection hour burden estimate for NDA waiver requests is included in Table 1 of this document under estimates for §§ 314.50, 314.60, 314.70, and 314.71.)

Section 314.93 sets forth requirements for submitting a suitability petition in accordance with 21 CFR 10.20 and 10.30. (Section 314.93 is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

The following sections in part 314 set forth requirements when submitting an abbreviated new drug application (ANDA).

Section 314.94(a) and (d) requires that an ANDA must contain the following and information: Application form; table of contents; basis for ANDA submission; conditions of use; active ingredients; route of administration, dosage form, and strength; bioequivalence; labeling; chemistry, manufacturing, and controls; samples; and patent certification.

Section 314.95 requires that notice of certification of invalidity or noninfringement of a patent to patent holders and NDA holders must be sent by ANDA applicants. (Section 314.95 is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.96 sets forth requirements for amendments to an unapproved application.

Section 314.97 sets forth requirements for submitting supplements to an approved ANDA for changes that require FDA approval.

Section 314.98(a) sets forth postmarketing adverse drug experience reporting and recordkeeping requirements. (Section 314.98(a) is already approved by OMB under 0910–0230 and 0910–0291 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.98(c) requires other postmarketing reports: Field alert reports (Form FDA 3331), annual reports (Form FDA 2252), and advertisements and promotional labeling (Form FDA 2253). (The information collection hour burden estimate for field alert reports is included in Table 1 of this document under § 314.81(b)(1); the estimate for advertisements and promotional labeling is included under § 314.81(b)(3)(i).)

Section 314.99(a) requires that sponsors must comply with certain reporting requirements for withdrawing an unapproved ANDA and for a change in ownership of an ANDA.

Section 314.99(b) sets forth requirements for sponsors who request waivers from FDA for compliance with §§ 314.92 through 314.99. (The information collection hour burden estimate for ANDA waiver requests is included in Table 1 of this document under estimates for §§ 314.94(a) and (d), 314.96, and 314.97.)

Section 314.101(a) requires that, if FDA refuses to file an application, the applicant may request an informal conference with FDA and request that the application be filed over protest.

Section 314.107(c)(4) requires notice to FDA by ANDA or 505(b)(2) application holders of any legal action concerning patent infringement. (Section 314.107(c)(4) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.107(e)(2)(iv) requires that an applicant must submit a copy of the entry of the order or judgement to FDA within 10 working days of a final judgement. (Section 314.107(e)(2)(iv) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.107(f) requires that an ANDA or 505(b)(2) applicants must notify FDA of the filing of any legal action filed within 45 days of receipt of the notice of certification. A patent owner may also notify FDA of the filing of any legal action for patent infringement. The patent owner or approved application holder who is an exclusive patent licensee must submit to FDA a waiver that waives the opportunity to file a legal action for patent infringement. (Section 314.107(f) is already approved by OMB under 0910–0305 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.110(a)(3) and (a)(4) requires after receipt of an FDA approvable letter, an applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (Section 314.110(a)(3) and (a)(4) is included under the parts 10 through 16 (21 CFR part 10 through 16) hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.110(a)(5) requires that, after receipt of an approvable letter, an applicant may notify FDA that it agrees to an extension of the review period so that it can determine whether to respond further.

Section 314.110(b) requires after receipt of an approvable letter, an ANDA applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (Section 314.110(b) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.120(a)(3) requires that, after receipt of a not approvable letter, an applicant may request an opportunity for a hearing on the question of whether there are grounds for denying approval of the application. (Section 314.120(a)(3) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.120(a)(5) requires that, after receipt of a not approvable letter, an applicant may notify FDA that it agrees to an extension of the review period so that it can determine whether to respond further.

Section 314.122(a) states that an ANDA or a suitability petition that relies on a listed drug that has been voluntarily withdrawn from sale must be accompanied by a petition seeking a determination whether the drug was withdrawn for safety or effectiveness reasons. (Section 314.122(a) is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.122(d) sets forth requirements for relisting petitions for unlisted discontinued products. (Section 314.122(d) is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document).

Section 314.126(c) sets forth requirements for a petition to waive criteria for adequate and well-controlled studies. (Section 314.126(c) is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.151(a) and (b) sets forth requirements for the withdrawal of and approval of an ANDA and the applicant's opportunity for a hearing and submission of comments. (Section 314.151(a) and (b) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and it is not included in the hour burden estimates in Table 1 of this document.)

Section 314.151(c) sets forth the requirements for withdrawal of approval of an ANDA and the applicant's opportunity to submit written objections and participate in a limited oral hearing. (Section 314.151(c) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.152(b) sets forth the requirements for suspension of an ANDA when the listed drug is voluntarily withdrawn for safety and effectiveness reasons, and the applicant's opportunity to present comments and participate in a limited oral hearing. (Section 314.152(b) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.161(b) and (e) sets forth the requirements for submitting and petition to determine whether a listed drug was voluntarily withdrawn from sale for safety or effectiveness reasons. (Section 314.161(b) and (e) is already approved by OMB under 0910–0183 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.200(c), (d), and (e) requires that applicants or others subject to a notice of opportunity for a hearing who wish to participate in a hearing must file a written notice of participation and request for a hearing as well as the studies, data, and so forth, relied on. Other interested persons may also submit comments on the notice. This section also sets forth the content and format requirements for the applicants' submission in response to notice of opportunity for hearing. (Section 314.200(c), (d), and (e) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.200(f) requires that participants in a hearing may make a motion to the presiding officer for the inclusion of certain issues in the hearing. (Section 314.200(f) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.200(g) requires that a person may respond to a proposed order from FDA denying a request for a hearing by providing sufficient data, information, and analysis to demonstrate that there is a genuine and substantial issue of fact which justifies a hearing. (Section 314.200(g) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.420 states that an applicant may submit to FDA a drug master file in support of an application, in accordance with certain content and format requirements.

Section 314.430 states that data and information in an application are disclosable under certain conditions, unless the applicant shows that extraordinary circumstances exist. (Section 314.430 is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.530(c) and (e) requires that, if FDA withdraws approval of a drug approved under the accelerated approval procedures, the applicant has the opportunity to request a hearing and submit data and information. (Section 314.530(c) and (e) is included under the parts 10 through 16 hearing regulations, in accordance with § 314.201, and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.530(f) requires that an applicant must first submit a petition for stay of action before requesting an order from a court for a stay of action pending review. (Section 314.530(f) is already approved by OMB under 0910–0194 and is not included in the hour burden estimates in Table 1 of this document.)

Section 314.550 requires that applicants must submit all promotional materials to FDA for consideration during the preapproval review period. (Section 314.550 is already approved by OMB in ''Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use,'' which published in the **Federal Register** (62 FR 55408), and is not included in the hour burden estimates in Table 1 of this document.)

Based on information provided by the pharmaceutical industry for the number of ''hours per response,'' and based on submissions collected and data tabulated by FDA for the ''number of respondents,'' the ''number of responses per respondent,'' and the number of ''total annual responses,'' FDA estimates the burden of this collection of information as follows:

TABLE 1.—Estimated Annual Reporting Burden[1]

21 CFR Section/Form	No. of Respondents	No. of Responses per Respondents	Total Annual Responses	Hours per Response	Total Hours
314.50(b), (c), (d), (e), (f), and (k)	83	1.49	124	1,600	198,400
314.54	4	1.25	5	300	1,500
314.60	144	16.89	2,432	80	194,560
314.65	18	1.28	23	2	46
314.70 and 314.71	418	5.33	2,229	300	668,700
314.72	59	2.17	128	2	256
314.81(b)(1) (FDA 3331)	140	5	700	48	33,600
314.81(b)(2) (FDA 2252)	269	9.06	2,438	40	97,520
314.94(a) and (d)	117	3.96	464	480	222,720
314.96	315	12.43	3,915	80	313,200
314.97	152	19.74	3,000	80	240,000

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