II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/cdrh/pmapage.html.

Dated: October 23, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–28155 Filed 11–5–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0449]

''Draft Guidance for Industry: The Administrative New Animal Drug Application Process''; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry (#132) entitled ''The Administrative New Animal Drug Application Process.'' The guidance defines what an administrative new animal drug application (NADA) is, the procedures that should be followed before a sponsor submits an administrative NADA, and the intended timeframe for review of administrative NADAs.

DATES: Submit written or electronic comments on the draft guidance by January 21, 2003, to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

Submit written comments on the information collection requirements by January 6, 2003.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http:///www.fda.gov/dockets/ecomments. Comments should be identified with the full title of the draft guidance document and the docket number found in the heading of this document.

Submit written comments on the collection of information requirements to the Dockets Management Branch (address above). Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Gail Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1796, e-mail: gschmer1@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*) prohibits the introduction into interstate commerce of new animal drugs that are not the subject of an approved NADA. Section 512(b) of the act (21 U.S.C. 360b) and part 514 (21 CFR part 514) describe the information that must be submitted to FDA, specifically CVM, as part of an NADA. CVM encourages sponsors to submit data for review at the most appropriate and productive times in the drug development process. Sponsors may submit, and CVM intends to review, data in support of discrete technical sections during the investigation of the new animal drug. The guidance explains phased review and direct review, describes the technical sections, tells sponsors how they should submit data or information in support of a technical section for review, and tells sponsors how they should submit an administrative NADA.

An administrative NADA is an NADA that is submitted after CVM has reviewed all of the technical sections containing the information required for the approval of the new animal drug and CVM has issued a technical section complete letter for each of those technical sections.

II. Significance of Guidance

The level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking about the administrative NADA process. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statutes and regulations.

III. The Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 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.

Title: The Administrative New Animal Drug Application Process.

Description: The act prohibits the introduction into interstate commerce of new animal drugs that are not the subject of an approved NADA. Section 512(b) of the act and the regulations in part 514 describe the information that must be submitted to FDA, specifically to CVM, as part of an NADA.

CVM encourages sponsors to submit data and information for review at the most appropriate and productive times in the drug development process rather than submitting all data and information at one time. Sponsors may submit, and CVM intends to review, data or information in support of discrete technical sections during the investigation of the new animal drug. This process is known as phased review. Sponsors may submit part or all of the data and information needed to support a technical section in a phased submission. The data submitted in

support of each technical section are covered by an existing paperwork clearance under OMB control number 0910–0032. FDA is seeking new paperwork clearance for the cover letter, table of contents, and summary that should accompany each submission. The cover letter identifying the submission as a ''phased submission'' should: (1) Describe briefly the purpose of the submission and the information contained in it, (2) reference or attach any pertinent documentation regarding previous agreements or understandings between the sponsor and CVM, (3) identify persons CVM may contact regarding any specifics of the submission, and (4) convey any other information the sponsor considers important or necessary to facilitate the review of the submission. There are potentially eight technical sections: Chemistry, manufacturing and controls; effectiveness; target animal safety; human food safety; environmental impact; labeling; freedom of information (FOI) summary; and, all other information.

After a sponsor has received technical section complete letters for each technical section containing information required for the approval of the new animal drug, the sponsor may file an administrative NADA. The administrative NADA should include a cover letter identifying the submission as an ''Administrative NADA,'' a signed FDA Form 356V, a table of contents, summary, copies of the technical section complete letters for each required technical section, complete facsimile labeling, and the FOI summary.

The cover letters that should be provided with each submission and with the administrative NADA and the copies of technical section complete letters represent new paperwork.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Administrative NADA applications	190	.24	47	4	188
Phased submissions	190	1.31	250	2	500

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

FDA averaged the number of administrative NADA applications and phased submissions for the past 2 years. Hours per response took into account that cover letters submitted summarized information contained in the submission and did not require any new information.

IV. Comments

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

Submit written comments concerning the information collection requirements to the Dockets Management Branch. A copy of the document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may be submitted on the Internet at http://www.fda.gov/dockets/ecomments. Once on the Internet site, select 02D–0449 ''The Administrative New Animal Drug Application Process'' and follow the directions. A copy of this document may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm.

Dated: October 28, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–28257 Filed 11–5–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Senior Executive Service Performance Review Board Membership

The Health Resources and Services Administration (HRSA) announces the appointment of members to the HRSA Senior Executive Service (SES) Performance Review Board (PRB). This action is being taken in accordance with Title 5, U.S.C., Section 4314(c)(4) of the Civil Service Reform Act of 1978, which requires members of performance review boards to be published in the **Federal Register**.

The function of the PRB is to ensure consistency, stability and objectivity in SES performance appraisals, and to make recommendations to the Administrator, HRSA, relating to the performance of senior executives in the Agency.

The following persons will serve on the HRSA SES Performance Review Board:

Dennis P. Williams, Neil Sampson, Stephen R. Smith, Katherine M. Marconi, Mary J. Horner, Douglas Morgan, Patricia L. Mackey, Catherine A. Flickinger, Merle G. McPherson, William D. Hobson, Marcia K. Brand, Peter C. van Dyck, J. Henry Montes, James Macrae, Jon L. Nelson, Denise H. Geolot, Samuel Shekar, Kerry Nesseler, Deborah Parham.

For further information about the HRSA Performance Review Board, contact Ms. Wendy Ponton, HRSA Office of Human Resources and Development, 5600 Fishers Lane, Room 14A43, Rockville, Maryland 20857.

Dated: October 30, 2002.

Elizabeth M. Duke,

Administrator.

[FR Doc. 02–28153 Filed 11–5–02; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Patterns and Consequences of Alcohol Use in Non-Reservation Indians

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, regarding the opportunity for public