comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 15, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–21758 Filed 8–24–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. 00N–1399]

Presubmission Conferences

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its new animal drug regulations to describe the procedures to be followed for requesting, conducting, and documenting presubmission conferences. Under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Drug Availability Act of 1996 (ADAA), any person intending to file a new animal drug application (NADA) or supplemental (NADA) or to investigate a new animal drug is entitled to one or more conferences with FDA to reach an agreement establishing a submission or investigational requirement. This proposed regulation describes how a person would request a presubmission conference and describes the procedures for the conduct of the presubmission conference.

DATES: Submit written comments on the proposed rule by November 8, 2000. Submit written comments on the information collection provisions by September 25, 2000.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Gail L. Schmerfeld, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1620.

SUPPLEMENTARY INFORMATION:

I. Background

The ADAA (Public Law 104–250) was enacted on October 9, 1996. Section 512(b)(3) of the act (21 U.S.C. 360b(b)(3)), as amended by section 2(d) of the ADAA, provides that any person intending to file an NADA or supplemental NADA or to investigate a new animal drug is entitled to one or more conferences with FDA prior to such submission or during the investigation of a new animal drug. The purpose of such a conference is to reach an agreement establishing a submission or investigational requirement. A decision establishing a submission or investigational requirement can be changed only if: (1) FDA and the potential applicant mutually agree to modify the requirement, or (2) FDA by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the animal drug involved has appeared after the conference. If FDA determines that more than one field study is required to establish by substantial evidence that an intended use of a new animal drug is effective, FDA will provide written scientific justification for that decision within 25 calendar days of the conference. While section 512(b)(3) of the act does not entitle persons who intend to file an abbreviated new animal drug application (ANADA) to request a presubmission conference, such potential applicants are entitled to request presubmission conferences under this proposed rule.

Although the ADAA added a statutory entitlement to a presubmission conference, FDA's Center for Veterinary Medicine (CVM) had already been encouraging sponsors of NADA's to participate in conferences with FDA to discuss in detail what studies are necessary to demonstrate the safety and effectiveness of a new animal drug. In its experience with these presubmission conferences, FDA found that, as a result of this direct and detailed communication during the development and review of new animal drugs, fewer unusable studies were conducted and there were fewer delays in the review process. Consequently, companies saved resources and the marketing of new animal drugs became more expeditious. FDA's success with the use of presubmission conferences to establish submission requirements for new animal drugs was also reflected in its commitment to implement broad use of presubmission conferences as part of the President's reinventing government initiatives (e.g., ''Reinventing the Regulation of Animal Drugs,'' May 1996). The ADAA codifies FDA's use of presubmission conferences.

II. Description of Proposed Rule

The regulations being proposed by FDA would establish the procedures for requesting, conducting, and documenting presubmission conferences. Presubmission conferences will continue to be like those that were held between applicants and FDA prior to the enactment of the ADAA. The purpose of presubmission conferences is to allow FDA and a potential applicant, i.e., a person intending to investigate a new animal drug or to file an NADA, supplemental NADA, or ANADA, to discuss and reach agreement regarding a submission or investigational requirement. A submission or investigational requirement includes, among other things, identification of the number and types of studies that are necessary to demonstrate the safety and effectiveness of a new animal drug for the intended uses and conditions of use prescribed, recommended, or suggested in the proposed labeling for the new animal drug. Presubmission conferences give FDA and a potential applicant a means to identify the least burdensome appropriate requirements that have a reasonable likelihood of resulting in approval.

Meetings other than presubmission conferences may be necessary during the development and review of new animal drugs. Meetings in which the focus is other than to establish the safety and effectiveness data requirements for new animal drugs (e.g., meetings relating to administrative processes, protocol development, or label development) are not specifically covered by this proposed rule.

A. Definitions (Proposed § 514.3)

Proposed § 514.3 defines the terms ''potential applicant,'' ''presubmission conference,'' and ''presubmission conference agreement'' as those terms are used in 21 CFR part 514. ''Potential applicant'' means any person intending to investigate a new animal drug, file an NADA or supplement, or file an ANADA. One or more ''presubmission conferences'' may be needed to establish agreement regarding part or all of a submission or investigational requirement. Agreement on a submission or investigational requirement reached by a potential applicant and FDA in a presubmission conference(s) will be recorded in the ''presubmission conference agreement'' section of the memorandum of conference prepared by FDA and will be

binding upon both FDA and the potential applicant.

B. Presubmission Conferences (Proposed § 514.4)

Proposed § 514.4 describes procedures for requesting, conducting, and documenting a presubmission conference.

1. Requesting a Presubmission Conference

Under the proposed rule, a potential applicant could request a presubmission conference any time prior to filing an NADA, supplemental NADA, or ANADA, including before a potential applicant submits a notice of claimed investigational exemption for a new animal drug. In order to request a presubmission conference, a potential applicant would be required to submit to FDA a letter requesting a presubmission conference. FDA would have to receive the request for a presubmission conference at least 30 calendar days prior to the requested conference date. The potential applicant would identify the request as a request for a presubmission conference and would have to include a proposed agenda and a list of the expected attendees. FDA would, to the extent agency resources permit, make every effort to schedule the presubmission conference at the earliest time agreeable to both FDA and the potential applicant. In order to ensure a productive exchange of views and efficient use of FDA resources, a potential applicant would also be required to forward to FDA, at least 30 calendar days in advance of the scheduled conference date the following: A copy of any materials to be presented at the conference; a list of proposed indications for the new animal drug or, if available, a copy of the proposed labeling; and a copy of any relevant background material that provides the scientific rationale to support the potential applicant's position on an issue to be discussed during the conference. If such materials are not provided or are not sufficient to provide the basis for a meaningful discussion, FDA may elect to postpone the meeting until it receives sufficient materials.

2. Conducting a Presubmission Conference

A presubmission conference (or series of such conferences) would be directed primarily at establishing agreement between FDA and the potential applicant regarding part or all of a submission or investigational requirement. The potential applicant and FDA could each bring consultants to the presubmission conference.

3. Documenting a Presubmission Conference

Under the proposed rule, FDA would prepare a memorandum of conference summarizing the substance of each presubmission conference, including all key discussion points, decisions, recommendations, agreements reached regarding all or part of a submission or investigational requirement, disagreements, and action items. That portion of the memorandum of conference that documents any agreements reached regarding all or part of a submission or investigational requirement would be the ''presubmission conference agreement'' and would be denoted as such by a heading as such. FDA would provide a copy of this memorandum to the potential applicant and give the potential applicant 30 calendar days to request changes to or seek clarification of the substance of the memorandum. The potential applicant could elect to have the copy of the memorandum provided by mail, by facsimile, and/or by some electronic media. For purposes of calculating the 30 days, FDA would use the date the memorandum is mailed, facsimiled, or electronically transmitted from the Documents Control Unit, whichever is earlier. If a potential applicant were to request changes or clarification, such a request should be directed to the appropriate Division Director in CVM. A copy of FDA's original memorandum of conference and a copy of the memorandum with changes or clarification, as appropriate, would be made part of the administrative file. If a memorandum is silent on an issue, including one that was discussed during the conference or addressed by materials provided by the potential applicant for the conference, such silence cannot be construed as agreement between FDA and the potential applicant on the issue. A copy of the final memorandum would be provided to the potential applicant. FDA would file in the administrative record, but not review or consider binding in any way, a memorandum of conference prepared by a potential applicant.

If FDA determines that more than one field study is necessary to demonstrate effectiveness, in accordance with section 512(b)(3) of the act, it would provide, either separately or as part of a memorandum of conference, written scientific justification for its decision within 25 calendar days of the date such decision is made. FDA would not, however, provide such written scientific justification if the potential applicant voluntarily proposes to conduct more than one field study but FDA does not believe multiple studies are necessary. The potential applicant's proposal to conduct more than one field study would be documented in the memorandum of conference.

One study can be a study at a single location or a study in which data are collected from multiple locations. Results obtained in a single location study may be dependent on site specific factors (e.g., disease definition, concomitant treatment, diet, management practices, climate, field conditions, etc.). In such cases, the results, although significant with respect to that site, may not permit inferences to be made to the intended target animal population. If FDA requires one field study to be conducted at multiple locations, at the request of the potential applicant, FDA would provide verbal or written justification for requiring multiple locations. Written justification could be provided separately or as part of a memorandum of conference. FDA intends to issue guidance to industry regarding the use of field studies to provide substantial evidence of effectiveness.

Presubmission conference agreements would generally include timeframes for completion. The agreements would assume that the potential applicant would use due diligence to complete the drug development process within those timeframes and FDA would use due diligence to complete its reviews within reasonable timeframes. If a potential applicant were to fail to meet the terms of an agreement, the agreement would have no precedential value for subsequent agreements relating to the same new animal drug because standards may change over time. Similarly, agreements relating to one new animal drug would have no precedential value with respect to other new animal drugs because requirements may vary from drug to drug or intended use to intended use.

Agreements reached through a presubmission conference could be modified under the limited circumstances described in proposed § 514.4(g). Proposed § 514.4(h) describes how a potential applicant may breach an agreement. The act provides that FDA breaches an agreement if it unilaterally modifies the agreement without a written order determining that a substantiated scientific requirement essential to the determination of safety or effectiveness appeared after the conference. Proposed § 514.4(i) describes procedures for resolving disputes that may arise between a

potential applicant and FDA during the presubmission conference process.

FDA encourages potential applicants to meet with FDA at any time to discuss submission requirements.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

IV. Analysis of Impacts

FDA has examined the impact of the proposed rule under Executive Order 12866 and under Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities unless the rule is not expected to have a significant economic impact on a substantial number of small entities. As this proposed rule will not impose significant new costs on any firms, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that the proposed rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Under section 512(b)(3) of the act, as amended by the ADAA, any person intending to file an NADA or supplemental NADA or to investigate a new animal drug is entitled to one or more conferences prior to such submission to reach an agreement establishing a submission or investigational requirement. The purpose of a presubmission conference is to allow a potential applicant and FDA to discuss and to reach agreement regarding a submission or investigational requirement, including the number and types of studies that are necessary to demonstrate that a new animal drug is safe and effective for its intended uses.

Prior to the enactment of the ADAA, CVM had already been encouraging sponsors of NADA's to participate in conferences with FDA to discuss in detail what studies are necessary to demonstrate the safety and effectiveness of the particular new animal drug being investigated. FDA found that, as a result of this direct communication during the development and review of new animal drugs, both the drug development and review processes became more efficient. This proposed rule would implement the statutory entitlement to a presubmission conference and, thus, ensure that this benefit will continue where applicants request a presubmission conference. To the extent that this proposed rule would educate those in the industry that were not familiar with presubmission conferences, there will be further benefits as additional potential applicants realize efficiencies gained in the animal drug development and application process if they request a presubmission conference.

FDA is not able to make a precise estimate of the savings that industry has realized through the presubmission conferences up to this point, or of any increase in the number of presubmission conferences that may be requested as a result of this rule. There are many factors that determine the type and number of studies necessary to demonstrate the safety and effectiveness of new animal drugs. This proposed rule seeks to secure an avenue of communication between the agency and potential applicants through which both can agree on the studies needed for a certain drug, thereby reducing unnecessary studies and review periods.

It is possible, however, to forecast a range of savings that may be expected to result from any decrease in approval time resulting from the use of a presubmission conference. For this purpose, FDA estimated a straight-line increase of a prospective drug's sales revenues from the application's approval up to $5 million in the 10th year and then decreasing again to zero in the 20th year. Since many drugs attain sales much greater than $5 million, the agency estimate results in a rather conservative benefit. Assuming a pretax profit of 20 percent of sales revenue, FDA estimates the present value of the profits from a 1- to 6-month decrease in approval time at $20,000 to $120,000 using a 7 percent discount rate. Research costs saved by the firm from not conducting unnecessary studies would be added to this amount. Regardless of the exact reduction in the drug review period, since the presubmission conferences are voluntary, applicants would only be expected to request a conference if they expected the net benefit of the conference to be positive. The proposed rule would not impose any mandatory compliance costs.

V. Unfunded Mandates Reform Act of 1995

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $110 million.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

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: Presubmission Conferences

Description: The proposed regulation is intended to implement section 512(b)(3) of the act which entitles any person intending to file an NADA or supplemental NADA or to investigate a new animal drug to request one or more conferences with FDA to reach an agreement establishing a submission or investigational requirement. Prior to the enactment of section 512(b)(3) of the act, FDA encouraged sponsors to meet with FDA to discuss the number and types of studies necessary to demonstrate that a new animal drug is safe and effective. FDA found that these informal presubmission conferences increased the efficiency of the drug development and drug review processes. FDA is publishing this proposed regulation to describe how to request, conduct, and document a presubmission conference.

Proposed section 514.4(b) describes the information that must be included in a letter submitted by a potential applicant requesting a presubmission conference, including a proposed agenda and a list of expected participants. Proposed section 514.4(d) lists the information that must be provided by the potential applicant to FDA prior to a presubmission conference. This information includes a copy of any materials to be presented at the conference, a list of proposed indications or a copy of the proposed labeling for the product under consideration, and any background material that provides an adequate scientific rationale to support the potential applicant's position on issues listed on the proposed agenda for the conference. Proposed section 514.4(f) discusses the content of the memorandum of meeting that will be prepared by FDA and proposes to allow the potential applicant to seek clarification or correction of the memorandum.

Table 1 of this document provides, by relevant section, the estimated burden of requesting, preparing for, and participating in presubmission conferences. The numbers in the chart are based on recent consultation with several of the major research and development firms that are responsible for the development of new animal drugs. While FDA estimates that the proposed regulation would increase the annual paperwork burden associated with the submission of NADA's, supplemental NADA's, and abbreviated NADA's, and requests for guidance on investigational requirements, FDA believes this increase will be offset by the resulting efficiencies (e.g., eliminating the conduct of studies that are not needed to demonstrate safety and effectiveness, decreasing the requests from reviewers for additional or clarifying information during the review process).

Description of Respondents: Potential applicants

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
514.4(b)	190	1	190	7	1,330
514.4(d)	190	1	190	123	23,370
514.4(f)	190	1	190	16	3,040
Total					27,740

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

In compliance with section 3507(d) of the PRA, the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons may submit to OMB (address above) written comments regarding the information collection by September 25, 2000.

Lists of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 514 be amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

1. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

2. Section 514.2 is added to subpart A to read as follows:

§ 514.2 Definitions.

(a) *Potential applicant* means any person intending to:

(1) Investigate a new animal drug under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act),

(2) File a new animal drug application (NADA) or supplemental NADA under 512(b)(1) of the act, or

(3) File an abbreviated new animal drug application (ANADA) under section 512(b)(2) of the act.

(b) *Presubmission conference* means one or more conferences between a potential applicant and FDA, requested by the potential applicant, to reach a binding agreement establishing a submission or investigational requirement.

(c) *Presubmission conference agreement* means that section of the memorandum of conference headed ''Presubmission Conference Agreement'' that records any agreement on the submission or investigational requirement reached by a potential applicant and FDA during the presubmission conference. The presubmission conference agreement will be binding on the potential applicant and FDA unless it is modified as described in § 514.5(g).

3. Section 514.5 is added to subpart A to read as follows:

§ 514.5 Presubmission conferences.

(a) *General.* Presubmission conferences provide a forum for a

potential applicant and FDA to reach agreement regarding the overall plan for conducting investigations of new animal drugs or obtaining approval of a new animal drug, including to discuss what studies are required to support approval of a new animal drug application (NADA), a supplemental NADA, or an abbreviated new animal drug application (ANADA), and to discuss the objectives and general design of particular studies. Presubmission conferences, as a project management tool, can enhance the animal drug development and evaluation process. The general principle underlying the conduct of any such conference is that there must be candid, full, and open communication about scientific or medical issues pertaining to the safety and effectiveness of an investigational new animal drug.

(b) *Requesting a presubmission conference.* A potential applicant is entitled to one or more conferences prior to the submission of an NADA, supplemental NADA, or an ANADA to reach an agreement establishing part or all of a submission or investigational requirement. Potential applicants must request a presubmission conference by submitting their request to the appropriate Center for Veterinary Medicine (CVM) Division Director in a signed letter. The letter must include a proposed agenda that clearly outlines the scope, purpose, and objectives of the presubmission conference and must list the names and positions of the representatives who are expected to attend the presubmission conference on behalf of the potential applicant.

(c) *Timing.* A potential applicant may request one or more presubmission conferences at any time prior to the filing of a NADA, supplemental NADA, or an ANADA. A request for a presubmission conference must be received by FDA at least 30 calendar days in advance of the requested conference date. FDA will schedule the presubmission conference at a time agreeable to both FDA and the potential applicant.

(d) *Advance information.* The potential applicant must provide to FDA, at least 30 calendar days in advance of a scheduled presubmission conference, a copy of any materials to be presented at the conference, a list of proposed indications or a copy of the proposed labeling for the product under consideration, and any background material that provides an adequate scientific rationale to support the potential applicant's position on issues listed on the proposed agenda for the conference. If the materials are not provided or are not sufficient to provide the basis for meaningful discussion, FDA may elect to postpone the meeting until sufficient materials are provided to FDA.

(e) *Conduct of a presubmission conference.* The potential applicant and FDA may each bring consultants to the presubmission conference. The presubmission conference(s) will be directed primarily at establishing agreement between FDA and the potential applicant regarding a submission or investigational requirement. The submission or investigational requirement will include the number and types of studies that are necessary to demonstrate the safety and effectiveness of a new animal drug for the intended uses and conditions of use prescribed, recommended, or suggested in the proposed labeling for the new animal drug.

(f) *Documentation of a presubmission conference*—(1) *Memorandum of conference.* FDA will prepare a memorandum of each conference summarizing the substance of the conference: Key discussion points, decisions, recommendations, agreements reached regarding all or part of a submission or investigational requirement, disagreements, and action items. That portion of the memorandum of conference that documents any agreements reached regarding all or part of a submission or investigational requirement will be included under the heading ''Presubmission Conference Agreement.'' FDA will provide a copy of the memorandum to the potential applicant for review. The potential applicant will have 30 calendar days from the date a copy of the final draft of the memorandum is provided to the applicant to request changes to or clarification of the substance of the memorandum. For purposes of calculating the 30 days, FDA will use the date the memorandum is mailed, facsimiled, or electronically transmitted to the potential applicant from the Document Control Unit, whichever is earlier. If a potential applicant requests changes or clarification, such request should be directed to the appropriate CVM Division Director. A copy of FDA's original memorandum of conference and a copy of the memorandum with changes or clarification, as appropriate, will be made part of the administrative file. If a memorandum is silent on an issue, including one that was discussed in the conference or addressed by materials provided for the conference, such silence cannot be construed as agreement between FDA and the potential applicant on the issue. FDA will provide the potential applicant with a copy of the final memorandum.

(2) *Field studies.* If FDA requires more than one field study to establish by substantial evidence that the new animal drug is effective for its intended uses under the conditions of use prescribed, recommended, or suggested in the proposed labeling, FDA will provide written scientific justification for requiring more than one field study. Such justification must be provided no later than 25 calendar days after the date of the conference at which the requirement for more than one field study is established. If FDA does not believe more than one field study is required but the potential applicant voluntarily proposes to conduct more than one field study, FDA will not provide such written justification. If FDA requires one field study to be conducted at multiple locations, FDA will, at the request of the potential applicant, provide written or verbal justification for requiring multiple locations.

(g) *Modification of presubmission conference agreements.* An agreement made under a presubmission conference requested under section 512(b)(3) of the Federal Food, Drug, and Cosmetic Act and documented in a memorandum of conference is binding on the potential applicant and FDA and may only be modified if:

(1) FDA and the potential applicant mutually agree to modify, in part or in whole, the agreement and such modification is documented and provided to the potential applicant as described in paragraph (f)(1) of this section; or

(2) FDA by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the new animal drug appeared after the conference.

(h) *When the terms of a presubmission conference agreement are no longer binding.* (1) A presubmission conference agreement will no longer be binding if:

(i) The potential applicant makes to FDA, before, during, or after the presubmission conference, any untrue statement of material fact; or

(ii) The potential applicant fails to follow any term of the agreement; and

(2) A presubmission conference agreement may no longer be binding if the potential applicant submits false or misleading data relating to a new animal drug to FDA.

(i) *Dispute resolution.* FDA is committed to resolving differences between a potential applicant and FDA reviewing divisions with respect to requirements for the investigation of new animal drugs and for NADA's,

supplemental NADA's, and ANADA's as quickly and amicably as possible through a cooperative exchange of information and views. When administrative or procedural disputes arise, a potential applicant should first attempt to resolve the matter within the appropriate review division beginning with the individual(s) most directly assigned to review of the application or investigational exemption. If the dispute cannot be resolved after such attempts, the dispute shall be evaluated and administered in accordance with applicable regulations (21 CFR 10.75). Dispute resolution procedures may be further explained by guidance available from CVM.

Dated: August 17, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–21692 Filed 8–24–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD07–00–006]

RIN 2115–AE 47

Drawbridge Operation Regulations; Longboat Pass and New Pass, Longboat Key, FL

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: In response to a request from Manatee County and after reviewing opening data for the bridges, the Coast Guard proposes to change the regulations governing the operation of the State Road 789 drawbridge across Longboat Pass, Manatee County and New Pass, Sarasota County, in Longboat Key, Florida. The changes would provide continuous drawtender attendance at Longboat Pass Bridge and remove the existing timed opening schedule for the New Pass Bridge. This action should accommodate the needs of vehicle traffic and better provide for the reasonable needs of navigation.

DATES: Comments and related material must be received by October 24, 2000.

ADDRESSES: You may mail comments and related material to Commander (obr), Seventh Coast Guard District, 909 SE 1st Avenue, Miami, Florida 33131–3050, or may be delivered to room 406 at the above address between 7:30 a.m. and 4 p.m. Monday through Friday, except Federal holidays. The Commander, Seventh Coast Guard District, maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection and will be available for inspection or copying at Commander (obr), Seventh Coast Guard District 909 SE 1st Avenue, room 406, Miami, FL 33131, between 8 a.m. and 4 p.m. Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Barry Dragon, Project Officer, Seventh Coast Guard District, at (305) 415–6730.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking, [CGD7–00–006], and indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us please enclose a stamped, self-addressed postcard or envelope. We will consider all comments received during the comment period. We may change this proposal in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to us at Seventh Coast Guard District (obr), 909 SE 1st Avenue, Room 406, Miami, FL 33133–3050 at the address under **ADDRESSES**, explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

Existing regulations in 33 CFR 117.299 require the Longboat Pass Bridge to open on signal from 6 a.m. to 6 p.m.. From 6 p.m. to 6 a.m. the bridge is not tended and requires 3 hours advance notice to open. The number of openings has increased at the bridge from 3,825 in 1997 to 4,499 in 1999. In addition, some boaters have reported difficulties obtaining openings at night when the bridge is not tended. Manatee County asked that the bridge be required to open on signal at all times.

Existing regulations in 33 CFR 117.311 require the New Pass Bridge to be attended at all times and provide for timed openings from 7 a.m. to 6 p.m. on the hour, 20 minutes past the hour, and forty minutes past the hour. Continual shoaling of New Pass has rendered it not navigable except for shallowest draft vessels. Consequently, the number of openings has continually decreased from 6942 in 1975, to 3847 in 1982 to 1367 in 1998. Manatee County asks that the bridge no longer operate on timed openings and that the bridge not be tended from 6 p.m. to 6 a.m.

Discussion of Rule

This proposal would amend 33 CFR 117.299 to require constant, on signal bridgetender service. The proposal would amend 33 CFR 117.311 to require on signal openings between 6 a.m. and 6 p.m. with 3 hours advance notice required between 6 p.m. and 6 a.m. These changes meet the increased need for openings at the Longboat Pass bridge because of the increased vessel traffic there, while allowing for less openings and untended periods at the New Pass bridge because of the significant decrease in vessel traffic there. The telephone number to call for an after-hours opening would be (941–359–5666).

Regulatory Evaluation

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a) (3) of that order. The office of Management and Budget has not reviewed it under that order. It is not significant under the regulatory polices and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). We expect the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary. We conclude this because there are no economic impacts in this proposal.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small