DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 91

[Docket No. FAA–2001–11133; Amendment No. 91–282]

RIN 2120–AH19

Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: The FAA is correcting an inadvertent error in a final regulation published in the **Federal Register** of Tuesday, July 27, 2004 (69 FR 44772). The regulation related to the certification of aircraft and airmen for the operation of light-sport aircraft. The correction is to the section concerning aircraft having experimental certificates: Operating limitations.

DATES: The regulation is effective September 4, 2004.

FOR FURTHER INFORMATION CONTACT: Susan Gardner, Flight Standards Service, General Aviation and Commercial Division (AFS–800), Federal Aviation Administration, 800 Independence Ave., SW., Washington, DC 20591; telephone 907–271–2034, or 202–267–8212.

SUPPLEMENTARY INFORMATION: In FR Doc. 04–16577 appearing on page 44772 in the **Federal Register** of Tuesday, July 27, 2004, make the following correction:

§ 91.319 [Corrected]

■ On page 44881, in the first column, amendment number 64, ''Amend § 91.319 by redesignating paragraph (e) as paragraph (h) and adding new paragraphs (e), (f), and (g) to read as follows:'' is corrected to read ''Amend § 91.319 by redesignating paragraph (e) as paragraph (i) and adding new paragraphs (e), (f), (g), and (h) to read as follows:''.

Issued in Washington, DC, on August 12, 2004.

Anthony F. Fazio,

Director, Office of Rulemaking.

[FR Doc. 04–18904 Filed 8–17–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. 2000N–1399]

Presubmission Conferences

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing this final rule to amend its new animal drug regulations to implement a new provision of the Federal Food, Drug, and Cosmetic Act (the act). Under this new provision of 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 final rule describes the procedures for requesting, conducting, and documenting such presubmission conferences.

DATES: This rule is effective November 1, 2004.

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

Congress enacted the ADAA on October 9, 1996. Section 512(b)(3) of the act (21 U.S.C. 360b(b)(3)), as amended by the ADAA, provides that any person intending to file an NADA or supplemental NADA or to request an investigational exemption is entitled to one or more conferences with FDA prior to such submission to reach an agreement establishing a submission or investigational requirement. In the **Federal Register** of August 25, 2000 (65 FR 51782), we proposed amending the new animal drug applications regulations in part 514 (21 CFR part 514) to describe the procedures to be followed for requesting, conducting, and documenting presubmission conferences. Under the proposed rule and final rule, persons intending to file an abbreviated new animal drug application (ANADA) as well as persons intending to file an NADA or supplemental NADA are entitled to request presubmission conferences. FDA provided 75 days for public comment on the proposed rule.

II. Comments on the Proposed Rule

We received four letters from government, industry, and trade associations commenting on the proposed presubmission conference rule. Our response to the comments, grouped by codified section, follows.

A. General Comments

(Comment 1) Two comments assert that presubmission conferences under section 512(b)(3) of the act represent a fundamental change in the manner the agency is to operate and a new way for the agency to do business.

(Response) FDA disagrees with these comments. Presubmission conferences under 512(b)(3) of the act do not represent a fundamental change in the manner we operate. Although there was no statutory or regulatory entitlement to a presubmission conference prior to enactment of the ADAA, FDA's Center for Veterinary Medicine (CVM) had already been encouraging sponsors of NADAs to participate in conferences with us to discuss in detail what studies would be necessary to demonstrate the safety and effectiveness of particular new animal drugs being investigated. We found, as a result of this direct communication during the development and review of new animal drugs, that fewer unusable studies were conducted and there were fewer delays in the review process. Although such agreements were not legally binding, we attempted to be sensitive to industry's concern that we not change such requirements without justification. Our goal was to not change requirements unless we became aware of new information that suggested such requirements may no longer support approval.

B. Definitions (§ 514.3)

In the proposed rule, the preamble discusses definitions in proposed § 514.3. However, the *Definitions* section in the codified text in the proposed rule was mistakenly numbered § 514.2. The definitions added by this final rule will be added to existing § 514.3 *Definitions* in alphabetical order.

In the proposed rule, *potential applicant* was defined to mean 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. Under § 514.5(c), a potential applicant may request one or more presubmission conferences prior to the filing of a NADA, supplemental NADA, or an ANADA. Thus, a person investigating a new animal drug under section 512(j) of the act is also a potential applicant. We are revising the definition of ''*potential applicant*'' to include ''any person investigating a new animal drug under section 512(j).''

In the proposed rule, the last sentence in the definition of *presubmission conference* agreement stated that ''The presubmission conference will be binding on the potential applicant and FDA unless it is modified as described in § 514.4(g).'' We are deleting this sentence because it is unnecessary. As defined in the proposed and final rule, a presubmission conference is binding.

(Comment 2) One comment expresses concern that the discussion in the preamble to the proposed rule appeared to limit presubmission conferences to just safety or effectiveness data generation.

(Response) The specific statement that raised the concern appeared in the second section entitled ''Description of the Proposed Rule,'' ''* * *. Meetings in which the focus is other than to establish the safety and effectiveness data requirement for new animal drugs (e.g.,* * *) are not specifically covered by this proposed rule'' (65 FR 51782 at 51783).

We did not intend that statement to be read to limit which meetings will be considered presubmission conferences. Most, if not all, investigational and submission requirements relate to establishing safety or effectiveness data requirements.

The key factor in determining whether a meeting is a presubmission conference is, as implied in section 512(b) of the act and the definition of *presubmission conference* in § 514.3(b), whether such meeting is ''* * * to reach a binding agreement establishing a submission or investigational requirement.'' Generally, the goal of a presubmission conference is to reach agreement on some or all of the investigational or submission requirements for a particular new animal drug. But, so long as the intent of a meeting is to discuss investigational or submission requirements, it is a presubmission conference even if the parties are unable to reach agreement.

However, there may be some meetings that are not related to the establishment of investigational or submission requirements that will not be covered by this regulation because they are not presubmission conferences. For example, a meeting requested by a company to present information about all of its ongoing research and development projects would not be a presubmission conference. Furthermore, a meeting to discuss a pending submission would not be a presubmission conference. As the term ''presubmission'' implies, submission requirements should be discussed before we receive a submission. Meetings to discuss pending submissions could give potential applicants an unfair advantage because they could have the effect of requiring the review of the submission prior to the meeting, thus pushing the review up in the queue. Therefore, we neither anticipate meeting with potential applicants to discuss pending submissions, nor would any such meeting fall within 512(b)(3) of the act or this rule.

The proposed definition of *presubmission conference* limits *presubmission conferences* to conferences ''requested by the potential applicant.'' The act provides that any potential applicant is entitled to a presubmission conference. However, the act does not specify that requests for presubmission conferences may be initiated only by potential applicants. Thus, we are revising the definition of *presubmission conference* to remove this restriction. While, typically, potential applicants will initiate requests for meetings to discuss investigational or submission requirements, FDA may encourage potential applicants to request a presubmission conference if we believe such a meeting may facilitate the development of data to support approval.

(Comment 3) One comment expresses concern that the binding nature of presubmission conferences results in a process that appears to be somewhat inflexible. The comment notes that a new animal drug (i.e., the formulation) or its proposed uses (i.e., the intended uses or conditions of use) may change as the product is developed and was concerned that data requirements may change in the time it takes FDA to draft and clear the presubmission conference agreement.

(Response) The act requires that agreements reached in presubmission conferences be binding. However, the act also provides flexibility by allowing for changes to such agreements if FDA and the applicant or requester mutually agree to modify the requirement, or if FDA determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the animal drug involved appears after the conference. Thus, although the parties may agree to modify a presubmission conference agreement, FDA cannot unilaterally change the agreement unless there are valid scientific reasons for doing so.

To ensure that investigational and submission requirements do not become outdated before a presubmission conference agreement is sent to a potential applicant, we are revising § 514.5(f)(1) in the final regulation (as described in the following paragraphs) to add a timeframe in which we will send a copy of the memorandum of conference, which includes any presubmission conference agreement, to the potential applicant to review.

(Comment 4) One comment requests that the regulations make it absolutely clear that the sponsor should be able to determine, with certainty, through a presubmission conference all the studies necessary to establish the human safety, animal safety, and efficacy of a new animal drug. Another comment expresses concern that the regulation describes a process that appears to be somewhat inflexible because, among other things, it requires us to establish investigational or submission requirements for new animal drugs that may change (e.g., in formulation, intended uses, and conditions of use) based on information gathered throughout their development.

(Response) The act and this final regulation provide both certainty and flexibility in determining investigational or submission requirements. First, the act and the regulation specifically state that any person intending to file a NADA or a request for investigational exemption is entitled to one or more conferences in order to reach agreement on certain submission requirements (section 512(b)(3) of the act and § 514.5(b)). Second, the act and the regulation specify that an agreement may be changed if the following conditions are met: (1) FDA and the applicant or requester 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 (section 512(b)(3) of the act and § 514.5(g)). Thus, the presubmission conference process provides certainty absent unforeseen circumstances, but provides means to address contingencies that may arise during new animal drug development.

The provision entitling a potential applicant to one or more presubmission conferences is intended to recognize that it may not be possible to establish

all of the investigational or submission requirements in one presubmission conference because the new animal drug or its proposed uses may change as it is being developed. The statute and regulation do not preclude the parties from reaching agreement regarding all the studies necessary to establish the human safety, animal safety, and effectiveness of a new animal drug in a single presubmission conference. However, we believe it is more likely that for most new animal drugs the parties will participate in a series of presubmission conferences.

Potential applicants may choose to and are encouraged to request more than one presubmission conference. For example, if the outcome of one study required to satisfy one of the approval requirements is likely to affect the number or types of additional studies that would be needed to satisfy the same or a different approval requirement, or if it may affect the formulation or proposed uses of the new animal drug. By sequencing presubmission conferences, a potential applicant may be able to avoid conducting studies that will not support or be necessary for approval.

Potential applicants should consider requesting presubmission conferences on specific, manageable issues and should include in the advance material to us all relevant information and data available to date. Potential applicants should also consider the sequencing of such conferences so that information and data on which future requirements may depend are available. For example, a potential applicant may request one presubmission conference to discuss the number and types of studies necessary to demonstrate safety and request another presubmission conference to discuss studies necessary to demonstrate effectiveness after they have conducted studies to demonstrate that a particular dose or dosage range is safe.

C. General (§ 514.5(a))

We are renaming this section ''General Principle Underlying the Conduct of a Presubmission Conference.'' We are deleting the first two sentences of proposed § 514.5(a). Although these sentences accurately reflect our view that a presubmission conference is the forum for a potential applicant and FDA to reach agreement regarding investigational or submission requirements and that the goal of such a conference is to enhance the animal drug development and evaluation process, these sentences do not set forth requirements or expectations and should not be included in the codified language.

We are keeping the last sentence, but changing it to read as follows: ''The general principle underlying the conduct of any presubmission conference is that there should be candid, full, and open communication.'' We believe it is important that all participants to a presubmission conference, potential applicants and FDA representatives alike, understand that candid, full, and open communication is essential to ensuring that such conferences will enhance the animal drug development and evaluation process.

D. Requesting a Presubmission Conference (§ 514.5(b))

We are revising the second sentence of proposed § 514.5(b) to read more clearly: ''A potential applicant's request for a presubmission conference must be submitted to FDA in a signed letter.'' If an investigational new animal drug file has not been established prior to receiving a request for a presubmission conference, our general practice is to establish an investigational new animal drug file for administrative reasons such as recordkeeping and protecting the confidentiality of information submitted by potential applicants.

E. Advance Information (§ 514.5(d))

We are revising proposed § 514.5(d), among other things, to clarify what information is required to be submitted to FDA in advance of a presubmission conference. Proposed § 514.5(d) specified that:

> The potential applicant must provide to FDA, at least 30 days before 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.

Under § 514.5(b), a potential applicant is required to provide a proposed agenda with their request for a presubmission conference. We are revising § 514.5(d) to clarify that a potential applicant is required to submit a detailed agenda as part of the advance materials submitted to FDA at least 30 calendar days before the scheduled meeting. We expect that many potential applicants will schedule presubmission conferences more than 30 days before the date they want to meet with FDA so that they can increase the likelihood that the appropriate staff representing the potential applicant and FDA will be available to meet on a particular date or within a particular timeframe. If the agenda is drafted at the time the meeting is requested, the potential applicants may not be able to provide the detail and focus for each of the agenda items at the level that is needed for reviewers to prepare for the presubmission conference. The proposed agenda submitted at the time of the request should identify the general areas of discussion and provide enough information to allow us to evaluate who from FDA should attend the meeting. But, we also need a detailed agenda at least 30 days before the presubmission conference is scheduled so that attendees can prepare for a productive discussion of the issues.

What constitutes a ''detailed agenda'' will depend on the purpose of the presubmission conference. The question the potential applicant should ask in preparing a detailed agenda is ''what information is necessary for a full and productive discussion on the issues identified in the agenda?'' Consistent with this revision, we are removing the word ''proposed'' that appears before agenda at the end of the first sentence in proposed § 514.5(d).

Proposed § 514.5(d) also required the potential applicant to provide to FDA ''* * * a list of proposed indications or a copy of the proposed labeling for the product under consideration* * *.'' We are revising § 514.5(d) to require submission of a list of proposed indications and also to require a copy of proposed labeling, if available.

We encourage potential applicants to develop proposed labeling early in the drug development process. By proposed labeling we mean that textual portion of the label that describes, among other things, the new animal drug, dosage form, route of administration, and the intended uses and conditions of use for the new animal drug at a level of specificity appropriate to the stage of development. Because this wording often drives the submission or investigational requirements, proposed label would assist us in establishing appropriate requirements.

Finally, we are adding the words ''a copy of'' and deleting the word ''adequate'' to clarify that a potential applicant is required to provide ''a copy of any background material that provides scientific rationale to support the applicant's position on issues listed in the agenda for the conference.'' We do not need originals of the background material. Readable copies may be provided in lieu of originals. The background material should provide a scientific rationale for the applicant's position on issues listed in the detailed agenda. We will determine after review

and discussion at the presubmission conference whether the materials provide ''adequate'' scientific rationale to support such positions.

(Comment 5) One comment states that, based on their experience with FDA, if the amount of advance information requested in the proposed rule is provided, there may be little opportunity for dialog or need for the meeting because the agency will have made its decisions prior to the actual meeting. Two comments suggest rather than requiring all information to be submitted prior to the meeting, providing background materials to acquaint participants with information that will be discussed should be sufficient.

(Response) The goal of a presubmission conference is to reach agreement regarding some or all of the investigational or submission requirements. If we are to be prepared for a meeting, and prepared to make binding decisions at such a meeting, sufficient scientific background materials must be provided in advance for our review and consideration. That does not mean that we will not be open to discussion. In fact, having the material in advance will allow our participants to prepare for a productive discussion because they will be able to formulate appropriate questions, conduct further research on issues, and apply their review experience, as appropriate.

It should be easier for potential applicants to provide copies of all material they evaluated or referenced relating to an issue listed in the agenda, rather than selecting or summarizing relevant material. FDA participants should have the opportunity to review all documentation in order to exercise their scientific judgment and, in many cases, years of experience reviewing new animal drugs to determine what information is relevant. If potential applicants select what information is submitted or not submitted, FDA participants may not have all the materials needed to make the decision or to provide the best advice to the potential applicants regarding the least burdensome investigational or submission requirements that are likely to result in approval.

(Comment 6) One comment believes there should be a mechanism for FDA to ask the applicant questions or request additional information via telephone call or e-mail, rather than delay the meeting. The comment hopes delays in holding a presubmission conference will be the exception, not the norm.

(Response) Nothing in this rule prevents FDA staff from contacting a potential applicant to ask clarifying questions or to request minor (i.e., nonvoluminous, noncomplex) additional information. If questions can be answered and minor additional materials can be provided to us in a timely manner prior to the presubmission conference, there would be no need to postpone a meeting.

The advance materials must permit a productive discussion of the issues, and if we are to reach a binding agreement with a potential applicant, sufficient information on which to make an informed decision. Whether and how often presubmission conferences are delayed will depend in part upon the quality and completeness of the advance materials submitted by the potential applicant.

We are revising the last sentence in proposed § 514.5(d) to clarify that: ''* * * FDA may elect to postpone part or all of the meeting until sufficient materials are provided to FDA.'' If sufficient materials are available to proceed with a productive discussion on some issues but not others, we intend to meet with the potential applicant to discuss those issues for which sufficient advance materials have been provided, if the issues are severable. Our goal is to assist potential applicants in moving forward with the development and approval of new animal drugs.

F. Conduct of a Presubmission Conference (§ 514.5(e))

We are revising the last sentence of proposed § 514.5(e) to clarify that: ''The submission or investigational requirement may include, among other things, the number, types, and general design of studies that are necessary to demonstrate the safety and effectiveness of a new animal drug.'' We are changing ''will'' to ''may'' because any particular submission or investigational requirement may include the number, types, general design, or some combination of these elements, of studies that are required to demonstrate safety and effectiveness, but not all of them. We are adding the phrase ''among other things'' because requirements may address issues other than number, type, or general design of studies, e.g., labeling requirements or methods validation. The first sentence of proposed § 514.5(a) stated that presubmission conferences provide a forum to discuss the objectives and general design of particular studies. Because we are deleting that sentence in the final rule, we are clarifying in final § 514.5(e) that submission or investigational requirements may include the general design of the studies.

G. Documentation of a Presubmission Conference (§ 514.5(f))

We are revising the first sentence in proposed § 514.5(f)(1) to clarify the contents of the memorandum of conference. ''FDA will prepare a memorandum for each presubmission conference that will include, among other things: any background information pertinent to the request for the meeting; a summary of the key points of discussion; agreements; and action items and assignments of responsibility.'' Other changes to § 514.5(f)(1) are described in the responses to comments that follow. Further, we are dividing final § 514.5(f)(1) into paragraphs to improve clarity and readability.

(Comment 7) One comment seems concerned that the presubmission conference agreement is part of the memorandum of conference. Further, the comment suggests that it may be more expeditious and timely for the registrant to prepare the memorandum of understanding with subsequent approval by the agency.

(Response) We note that the comment uses the term ''memorandum of understanding.'' Neither FDA nor potential applicants draft memorandum of understanding to document presubmission conferences. As defined in FDA's Staff Manual Guide 2830.1, the term ''Memoranda of Understanding'' is primarily used by FDA to refer to formal agreements between FDA and other Government (Federal, State, or local) agencies. We assume that the comment meant ''memorandum of conference.''

As discussed in the proposed rule, 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'' (65 FR 51782 at 51783). We believe it is more efficient for us to prepare the memorandum of conference and that it is important to provide the agreement in the context of the information and discussions that took place during the presubmission conference.

We are revising the sentence in proposed § 514.5(f)(1) that read: ''If a memorandum is silent on an issue, * * * such silence cannot be construed as agreement between FDA and the potential applicant on the issue'' to clarify that it is specifically the presubmission conference agreement section of the memorandum in which silence does not constitute agreement.

This sentence logically follows the sentence explaining that the presubmission conference agreement is a section of the memorandum and will read as follows: ''If the presubmission conference agreement section of the memorandum is silent on an issue, including one that was discussed in the conference or addressed by materials provided for the conference, such silence does not constitute agreement between FDA and the potential applicant on the issue.''

(Comment 8) The preamble to the proposed rule states that presubmission conference agreements would generally include timeframes for completion. One comment acknowledges that scientific knowledge on which agreements are based may change over long periods of time, but expresses concern that no guidance on the duration of those timeframes was given.

(Response) Presubmission conference agreements will be based on scientific knowledge available at the time of the agreement. The inclusion of timeframes in a presubmission conference agreement is intended, as the comment notes, to recognize that the state of scientific knowledge may change over time. The inclusion of a timeframe signals to a potential applicant or us the need to revisit whether the submission or investigational requirements are still relevant after that time.

What constitutes a reasonable timeframe will vary significantly depending on, among other things, the nature of the product, the species for which the drug is intended, and the proposed uses. For example, time may affect the inferential value of data. Time-dependent factors include, e.g., genetics of the target animal and the target organism, husbandry practices, and diets (62 FR 59830 at 59833, November 5, 1997).

Timeframes and any other caveats should be discussed as part of the process of reaching agreement. Examples of other caveats that might be included in a presubmission conference agreement include specification of the formulation (e.g., final formulation) on which the studies should be conducted and timeframes for updating literature searches.

(Comment 9) All of the comments express concern that the proposed regulation does not include a timeframe in which FDA would issue the memorandum of conference, and thus, the presubmission conference agreement, if one is reached. Most comments suggest that FDA should be required to provide the memorandum of conference to the potential applicant within 25 days of the conference. They state that this timeframe is consistent with the timeframe in which FDA must provide written justification if it is requiring more than one field study to provide substantial evidence of effectiveness. One comment is specifically concerned that in the time it takes for the agreement to clear the agency, the submission or investigational requirements might change.

(Response) We agree that FDA should provide the memorandum of conference to the potential applicant in a timely manner and will provide the memorandum no later than 45 days after the date of the presubmission conference. Accordingly, we are revising the sentence in proposed § 514.5(f)(1) that read: ''FDA will provide a copy of the memorandum to the potential applicant for review'' to read: ''FDA will send a copy of the memorandum to the potential applicant for review no later than 45 calendar days after the date of the conference.''

We cannot provide the memorandum in 25 days because it is not a practical timeframe for issuing most memoranda of conference considering all of our other review responsibilities. Further, we expect that many agreements will relate to investigational or submission requirements other than those that relate to effectiveness and will not include a requirement for more than one field study. If we require more than one field study to provide substantial evidence of effectiveness, we will provide our justification for that requirement no later than 25 calendar days after the date of the conference as required by section 512(b)(3) of the act and as described in § 514.5(f)(2).

We are also revising the fourth sentence of proposed § 514.5(f)(1) to clarify that as follows: ''The potential applicant will have 30 calendar days from the date a copy of the memorandum of conference is sent to the applicant to request changes to, or clarification of, the substance of the memorandum.'' For purposes of calculating the timeframe for the potential applicant to respond, the only date of record from which we can calculate the time is the date the memorandum is sent. This sentence will follow the sentence that discusses that silence of a presubmission conference agreement on an issue does not constitute agreement.

We are removing the sentence in proposed § 514.5(f)(1) regarding calculation of the timeframe because this is an administrative matter and need not be addressed by regulation.

(Comment 10) Two comments note that the potential applicant is given 30 days to request changes to or seek clarification of FDA's memorandum of conference, but no timeframe is given in which FDA must respond to the potential applicant's request. One comment proposed that FDA respond within 25 days, another proposed 15 days.

(Response) We will send a response to the potential applicant's request for changes to or clarification of a memorandum of conference no later than 45 calendar days after the date such request is received. If we agree that the memorandum of conference needs to be changed to correct or clarify content, we will prepare an amended memorandum of conference and include a copy of the amended memorandum as part of our response to the potential applicant.

In the final rule, § 514.5(f)(1)(iii) will include a timeframe for FDA to send a response to a potential applicant's request for changes or clarification, and clarify the administrative steps relating to requesting and documenting changes to the presubmission conference agreement. Accordingly, the last three sentences of final § 514.5(f)(1) will read: ''If a potential applicant requests changes or clarification, the request must be sent to FDA. If the potential applicant requests changes or clarification, FDA will send the potential applicant a response to their request no later than 45 calendar days after the date of receipt of the request.'' The last sentence of § 514.5(f)(1)(iv), under the paragraph ''Administrative record,'' will read: ''A copy of FDA's original memorandum of conference and, as appropriate, a copy of an amended memorandum to correct or clarify the content of the original memorandum will be made part of the administrative file.''

We hope to minimize the need for changes to or clarification of the memorandum by summarizing at the close of each presubmission conference the key points of discussion, agreements, and action items, and the assignments of responsibilities for each of those items. That summary of key points will provide the potential applicant with the first and best opportunity to ensure that the discussions and any agreements reached will be accurately documented in the memorandum of conference. If the potential applicant disagrees with the summary presented at the end of the presubmission conference, the potential applicant should discuss the disagreement with us before the close of the presubmission conference. In the event the potential applicant finds, after reviewing FDA's memorandum of

conference, that correction to or clarification of the memorandum is needed, the potential applicant should request changes to or clarification of the memorandum by submitting a letter. Following the presubmission conference, FDA will only review a request for changes to or clarification of the memorandum that is submitted within 30 calendar days from the date a copy of the memorandum is sent to the applicant. The potential applicant should not request changes to or clarification of the memorandum of conference by submitting the potential applicant's version of the memorandum.

(Comment 11) The act, as amended by the ADAA, requires that FDA justify a requirement for more than one field study to provide substantial evidence of effectiveness. Two comments assert that FDA is attempting to circumvent the intent of the ADAA by indicating that it may require a single study in multiple locations.

The comments assert that the issue of whether a field study conducted at multiple sites using a single protocol is a single study or represents more than one study has long been an area of disagreement between industry and FDA. But, one comment acknowledges it may be true that, for some small animal clinical studies, multiple locations may be necessary to obtain sufficient numbers of patients.

(Response) FDA is not attempting to circumvent the intent of the ADAA. Whether a study conducted at multiple sites following the same protocol is most appropriately considered a single study or multiple studies depends upon the degree of coordination between the sites, the intent of the analysis, whether the data would be pooled to assess statistical significance, and the generalizability of the findings (inferential space). Although ADAA does not require FDA to provide justification for a multilocation field study, FDA has agreed that in the spirit of ADAA it will provide justification of the need for a multilocation field study (substantial evidence final rule at 64 FR 40746 at 40750, July 28, 1999). To that end, proposed § 514.5(f)(2) provided: ''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'' (64 FR 51786).

If we require more than one field study, we will provide written justification within 25 days of a conference why more than one field study is essential to demonstrate by substantial evidence that the new animal drug is effective. After further consideration FDA has decided that if we require one field study with multiple locations, we will provide both verbal justification for why more than one location is required during the presubmission conference and written justification as part of the memorandum of conference, which must be provided in accordance with this final rule no later than 45 days after the date of the conference. We are revising the last sentence of proposed § 514.5(f)(2) to clarify when and how we will provide justification for requiring multiple locations: ''If FDA requires one field study to be conducted at multiple locations, FDA will provide justification for requiring multiple locations verbally during the presubmission conference and in writing as part of the Memorandum of Conference.''

The principles governing the number and types of studies necessary to demonstrate by substantial evidence that a new animal drug is effective are addressed in § 514.4(b)(3) and, extensively, in the preambles to the proposed and final rules (62 FR 59830 and 64 FR 40746). The preambles to the proposed and final substantial evidence rule (62 FR 59830 at 59833 and 64 FR 40746 at 40749) further describe the considerations for designing a single adequate and well-controlled study that may demonstrate substantial evidence of effectiveness. A single multilocation study may be an accepted way of evaluating drugs efficiently if it is designed to provide independent substantiation and inferential value. In any instance, presubmission conferences give potential applicants a venue to discuss, among other things, the least burdensome requirements for demonstrating effectiveness.

H. Modification of Presubmission Conference Agreements (§ 514.5(g))

(Comment 12) One comment states that the **Federal Register** document for the proposed rule left §§ 514.4 or 514.5 open for future language that would specify how the presubmission conference agreement could be modified.

(Response) In both the proposed and final rule, the bases for modifying a presubmission conference are found in § 514.5(g). The preamble to the proposed rule stated that proposed § 514.4 describes procedures for requesting, conducting, and documenting a presubmission conference. These procedures were proposed, however, to be codified at § 514.5, not in § 514.4 of the proposed rule. In the final rule, these procedures are codified at § 514.5. Existing § 514.4 further defines substantial evidence.

I. When the Terms of a Presubmission Conference Agreement Are No Longer Binding (§ 514.5(h))

(Comment 13) Two comments believe the provisions in proposed § 514.5(h), when the terms of a presubmission conference are no longer binding, are outside the statutory authority of the agency. The act, as amended by the ADAA, provides that agreements regarding submission or investigation requirements reached at a presubmission conference shall bind the Secretary of Health and Human Services (the Secretary) and the applicant or requester except in two specific situations. The first is by agreement of both parties, and the second is where the Secretary, 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. The comments assert that the agency does not have the authority to create other mechanisms by which FDA can unilaterally declare presubmission conference agreements not binding.

(Response) We are revising the heading in proposed § 514.5(h), ''When the terms of a presubmission conference agreement are no longer binding'' to ''When the terms of a presubmission conference agreement are not valid.'' The heading in the proposed regulation did not accurately reflect the content or intent of the provision.

The intent of proposed § 514.5(h) was not to describe additional conditions under which a presubmission conference agreement is no longer binding. The intent of the provision was to emphasize that if presubmission conference agreements are to be meaningful and valid, they must be based on the truthful submission of information and must bind both parties. There cannot be agreement between parties if statements or representations made by one party are materially false, fictitious, or fraudulent. Thus, FDA considers agreements based on untrue statements or mispresentations of material facts to never have been valid. Further, if a party fails to follow any material term of the agreement, such agreements may become invalid.

We disagree with the comments that assert that the provisions in proposed § 514.5(h) are outside the statutory authority of the agency. As stated by one comment, no one should be untruthful or mislead the agency. In fact it is a crime to knowingly and willfully make an untruthful statement to FDA on matter within its jurisdiction; specifically, 18 U.S.C. 1001(a) provides:

Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United Stated, knowingly and willfully—

(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;

(2) makes any materially false, fictitious, or fraudulent statement or representation; or

(3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;

shall be fined under this title or imprisoned not more than 5 years, or both.

The ADAA does not limit or in any way affect the applicability of the criminal code to potential applicants who provide materially false, fictitious, or fraudulent information to FDA in the course of providing information to facilitate the conduct of a presubmission conference or to support new animal drug approval.

Further, section 701(a) of the act (21 U.S.C. 371(a)) vests in the Secretary the authority to issue regulations for the efficient enforcement of the act. No provision of the ADAA limits or supersedes the authority granted to the Secretary, and FDA by delegation, under section 701(a) of the act. FDA has the authority to make clear the conditions under which agreements were never valid or are no longer valid.

(Comment 14) Two comments are concerned by the provision in the proposed rule that stated: ''[a] presubmission conference agreement will no longer be binding * * * if the potential applicant fails to follow any term of the agreement.'' Both comments believe that it would be inequitable for an entire agreement to be voided if the applicant failed to comply with some nonmaterial portion of the agreement. One comment suggests that each component of the presubmission conference agreement should be judged upon its own merits and that failure to meet one provision of the agreement should not automatically invalidate the whole agreement. The other comment is particularly concerned that failure to meet timeframes provided for in presubmission conference agreements may frequently cause agreements to be invalidated.

(Response) We do not intend to invalidate an entire presubmission conference agreement if the potential applicant fails to follow immaterial term(s) of the agreement and the term(s) of the presubmission conference agreement are severable. Thus, we are adding ''material'' before the word term in § 514.5(h)(1)(ii). We intend to examine the severability of the terms of a presubmission conference agreement on a case-by-case basis.

For example, a determination of whether a timeframe is a material term of the agreement will be made by FDA on a case-by-case basis. We understand the comment's concern that timeframes included as terms of the presubmission conference agreement may result in invalidation of the presubmission conference agreement. However, we believe that steps have been built into the presubmission conference process to decrease the likelihood that timeframes will present a major obstacle to complying with the terms of the agreement. First, the potential applicant and FDA should discuss and agree to reasonable timeframes during the presubmission conference. Second, we have added timeframes for FDA to provide the memorandum, including the presubmission conference agreement, and our response to any requests for correction or clarification to ensure our timely response to potential applicants. Finally, we anticipate that the recent enactment of the Animal Drug User Fee Act of 2003 will minimize any significant delays that occur within FDA in reviewing submissions that may affect the potential applicant's ability to meet reasonable timeframes in the agreement.

III. Environmental Impact

This final rule clarifies the procedures for requesting, conducting, and documenting presubmission conferences. We have carefully considered the potential environmental impacts of this rule and determined that this action is of a type, as described in 21 CFR 25.30(h), 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

We have examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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). We believe that this final rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866. We have also determined that the rule is not a significant regulatory action as defined by the Executive order and, therefore, is not subject to review under the Executive order. Under the Regulatory Flexibility Act, if a regulation has a significant economic impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize the impact on small entities. FDA certifies in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) that this rule will not have a significant economic impact on a substantial number of small entities, and therefore, a regulatory flexibility analysis is not 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 presubmission conferences is to allow a potential applicant and FDA to reach agreement regarding a submission or investigational requirement, including the number and types of studies that are necessary to demonstrate that the 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 NADAs 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. We 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 final rule implements the statutory entitlement to a presubmission conference, and thus, it will ensure that this benefit will continue where potential applicants request a presubmission requirement.

FDA is not able to make a precise estimate of the savings that industry has realized through presubmission conferences, or of any increase in the number of presubmission conferences that may be requested as a result of the statutory entitlement. This final rule describes the procedures for requesting, conducting, and documenting presubmission conferences and secures an avenue of communication between us and the potential applicants through which both can agree on the studies needed for a certain drug, thereby reducing unnecessary studies and review periods.

In the proposed rule, we forecasted a range of savings that may be expected from any decrease in approval time resulting from a potential applicant requesting a presubmission conference. We 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 deceasing again to zero in the 20th year. Because many new animal drugs attain sales much greater than $5 million, we estimated results in a rather conservative benefit. Assuming pretax profit of 20 percent of sales revenue, we estimated 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, potential applicants would only be expected to request a presubmission conference if they expected the net benefit of the conference to be positive. We also concluded that the proposed rule would not impose any mandatory compliance costs.

We did not receive any comments that challenged our conclusions concerning the benefits or costs of the proposed rule. Further, the modifications made to this final rule would not lead us to change our conclusions concerning the aforementioned costs and benefits of the rule.

Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any regulation that may result in an expenditure by State, local and tribal governments in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this final rule because the 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 approximately $110 million.

V. Federalism

We have analyzed this final rule in accordance with the principles in Executive Order 13132. We have determined that the final 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, we have concluded that the final rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement has not been prepared.

VI. Paperwork Reduction Act of 1995

This final 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 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs 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.

Title: Presubmission Conferences

Description: This final rule 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 the section 512(b)(3) of the act, we 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. We found that these meetings increased the efficiency of the drug development and drug review processes. We are publishing this final rule to describe how to request, conduct, and document a presubmission conference.

Final § 514.5(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. Final § 514.5(d) lists the information that must be provided by the potential applicant to FDA at least 30 days prior to a presubmission conference. This information includes a detailed agenda, a copy of any materials to be presented at the conference, a list of proposed indications and, if available, a copy of the proposed labeling for the product under consideration, and a copy of any background material that provides scientific rationale to support the potential applicant's position on issues listed in the agenda for the conference. Final § 514.5(f) discusses the content of the memorandum of conference that will be prepared by FDA and gives the potential applicant an opportunity to seek correction to or clarification of the memorandum.

Description of Respondents: Potential applicants

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR	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 Hours					27,740

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

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 consultation with several of the major research and development firms that are responsible for the development of new animal drugs. While we estimate that the final regulation will increase the annual paperwork burden associated with the

submission of NADAs, supplemental NADAs, and abbreviated NADAs, and requests for guidance on investigational requirements, we believe this increase will be offset by the resulting efficiencies (e.g., eliminating the conduct of studies that are not needed to support approval, decreasing requests from reviewers for additional or clarifying information during the review process).

The information collection provisions of this final rule have been submitted to OMB for review.

Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List 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 and redelegated to the Center for Veterinary Medicine, 21 CFR part 514 is 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. 321, 331, 351, 352, 353, 360b, 371, 379e, 381.

■ 2. Section 514.3 is amended by adding the following definitions in alphabetical order:

§ 514.3 Definitions.

* * * * *

Potential applicant means any person:

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

(2) Investigating a new animal drug under section 512(j) of the act,

(3) Intending to file a new animal drug application (NADA) or supplemental NADA under section 512(b)(1) of the act, or

(4) Intending to file an abbreviated new animal drug application (ANADA) under section 512(b)(2) of the act.

Presubmission conference means one or more conferences between a potential applicant and FDA to reach a binding agreement establishing a submission or investigational requirement.

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.

* * * * *

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

§ 514.5 Presubmission conferences.

(a) *General principle underlying the conduct of a presubmission conference.* The general principle underlying the conduct of any presubmission conference is that there should be candid, full, and open communication.

(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. A potential applicant's request for a presubmission conference must be submitted to FDA 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 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 before a scheduled presubmission conference, a detailed agenda, a copy of any materials to be presented at the conference, a list of proposed indications and, if available, a copy of the proposed labeling for the product under consideration, and copies of materials evaluated or referenced relative to issues listed in the 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 part or all of 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 may include, among other things, the number, types, and general design 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*—(i) *Preparation.* FDA will prepare a memorandum for each presubmission conference that will include, among other things, any background pertinent to the request for meeting; a summary of the key points of discussion; agreements; and action items and assignments of responsibility. 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.'' If the presubmission conference agreement section of the memorandum is silent on an issue, including one that was discussed in the conference or addressed by materials provided for the conference, such silence does not constitute agreement between FDA and the potential applicant on the issue.

(ii) *Sending a copy to the potential applicant.* FDA will send a copy of the memorandum to the potential applicant for review no later than 45 calendar days after the date of the conference

(iii) *Requests for changes or clarification.* If a potential applicant requests changes to, or clarification of, the substance of the memorandum, the request must be sent to FDA within 30 calendar days from the date a copy of the memorandum is sent to the applicant. If the potential applicant requests changes or clarification, FDA will send the potential applicant a response to their request no later than 45 calendar days after the date of receipt of the request.

(iv) *Administrative record.* A copy of FDA's original memorandum of conference and, as appropriate, a copy of an amended memorandum to correct or clarify the content of the original

memorandum will be made part of the administrative file.

(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 provide justification for requiring multiple locations verbally during the presubmission conference and in writing as part of the memorandum of conference.

(g) *Modification of presubmission conference agreements.* An agreement made under a presubmission conference requested under section 512(b)(3) of the 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 not valid*—(1) A presubmission conference agreement will no longer be valid 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 material term of the agreement; and

(2) A presubmission conference may no longer be valid 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 NADAs, supplemental NADAs, and ANADAs 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 the 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 the Center for Veterinary Medicine.

Dated: August 10, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–18846 Filed 8–17–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Firocoxib

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Merial Ltd. The NADA provides for veterinary prescription use of firocoxib chewable tablets in dogs for the control of pain and inflammation associated with osteoarthritis.

DATES: This rule is effective August 18, 2004.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: *melanie.berson@fda.gov*.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640, filed NADA 141–230 for PREVICOX (firocoxib) Tablets. The application provides for the veterinary prescription use of firocoxib chewable tablets in dogs for the control of pain and inflammation associated with osteoarthritis. The NADA is approved as of July 21, 2004, and 21 CFR part 520 is amended by adding new § 520.928 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning July 21, 2004.

The agency has determined under 21 CFR 25.33(d)(1) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.928 is added to read as follows:

§ 520.928 Firocoxib.

(a) *Specifications.* Each chewable tablet contains 57 or 227 milligrams (mg) firocoxib.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* 5 mg per kilogram (2.27 mg per pound) body weight once daily.