



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUBJECT: **Comments on Docket No. 00N-1399, Presubmission Conferences**

The following comments are provided from USDA, Animal and Plant Health Inspection Service (APHIS) on FR V. 65, No. 166, pp 51782-51787, proposed rule on Presubmission Conferences:

The proposed rule on formalization of presubmission conferences is well intended to facilitate the registration of new animal drug applications (NADA), supplemental NADA, and abbreviated new animal drug applications (ANADA) for submission or investigational requirements.

A presubmission conference may allow the potential applicant or registrant to meet with Agency regulatory managers and science reviewers to basically accomplish the following:

- o *Introduce the potential applicant* to relevant Agency staff.
- o *Describe the potential product* to the best of the applicant's knowledge to Agency staff. The applicant may only have partial or incomplete knowledge to describe the product at the time of the presubmission meeting and more descriptive information often follows as the active ingredient is further refined and product formulations are developed.
- o *Describe the potential uses of the product* to the best of the applicant's knowledge to Agency staff. As above, potential uses may change as product development evolves or progresses.
- o *Determine if registration is required* according to the descriptive preliminary information provided by the applicant.
- o *Describe the registration process* to the potential applicant, as may or may not be necessary, according to the applicant's knowledge and experience.
- o Based on the preliminary or best information available at the time of the presubmission conference, *determine the probable investigational data requirements for registrations and possible data waivers* that may be applicable.



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- o Based on the preliminary or best information available at the time of the presubmission conference, *determine the probable investigational data requirements for registrations and possible data waivers* that may be applicable.
- o *Agree on subsequent actions*, as required, to advance the registration process and allow for the above contingencies of product evolution or development.

Depending on developing product descriptive information and evolving potential use patterns, the investigational data requirements may also change accordingly and, therefore, a degree of flexibility is needed in the registration process. With pesticides, the registrant may prepare a memorandum of understanding following the meeting that is not binding due to the possible contingencies that may subsequently arise, but is kept in the record for reference. Data requirements are communicated to the registrant by letter following application submission by the registrant.

The FR Notice describes a process that appears to be somewhat inflexible to meet the contingency needs for new product registrations. A "presubmission conference agreement" is proposed that is binding upon both FDA and the potential applicant. FDA would provide this memorandum. However, the FR Notice does not provide any time limitation after the presubmission meeting for FDA to provide the agreement document. As it is a "binding" document, it may take some time if subject to legal council review, leading to untimeliness and inefficiency due to evolving product development and use patterns. Data requirements may change accordingly. The proposed rule is very well meant to fill a need, but appears to impose additional processes that may inhibit flexibility to meet emerging contingencies often encountered in registration. A more flexible and responsive process to accommodate evolving needs would appear more beneficial. The potential applicant has 30 days to request changes or seek clarification of the substance of the memorandum. The FR Notice refers to the agreement as a memorandum, when it is also described as a binding agreement, essentially a contract with defined terms of cancellation. The proposed rule also holds a memorandum of understanding on the presubmission conference prepared by the potential applicant to be nonbinding, whereas, it may be more expeditious and timely for the registrant to prepare the memorandum of understanding with subsequent approval by the Agency.

The FR Notice states that FDA encourages applicants to meet with FDA at any time to discuss submission requirements and no conditions are given, but if the topic of the meeting includes investigational requirements, as would commonly be the case, then it appears to fall under the definition and requirements of a presubmission conference and require a binding agreement. Such meetings could be frequent in the evolving regulatory process and involve e-mail, telephone conferences, as well as actual meetings. Therefore, preparation of binding agreements would appear burdensome to FDA due to the frequency of discussions with registrants concerning investigational requirements and could impede the registration process. Methods of streamlining the process, while keeping appropriate legal documentation in the form of correspondence, would appear more expeditious than the contractual nature of the proposed rule.

Most USDA APHIS Wildlife Services products are unique, and Investigational New Animal Drugs (INADs) are necessary since the wildlife target species cannot be readily studied in the laboratory. In many cases, it may not be immediately known upon which species the product will eventually be useful. APHIS Wildlife Services may apply for an INAD on one species, waterfowl for example, but subsequently determine that a product is efficacious on pigeons or turkeys. Another problem that Wildlife Services encounters with products is the diminutive size of the market which precludes financial interest to pursue a fully registered use. However, the INAD use is valuable in managing wildlife populations, even under the restrictive conditions that may be imposed. It would be extremely difficult for FDA to draft a binding presubmission agreement when Wildlife Services has not yet defined the species on which the product may be used and does not ever foresee commercializing it. The FR Notice leaves Sec. 514.4 or .5 open for future language that would specify how the presubmission conference agreement could be modified. It will be important that this section of the rule allows the flexibility APHIS Wildlife Services requires.

USDA APHIS appreciates the opportunity to provide comments on the proposed rule.

Sincerely,

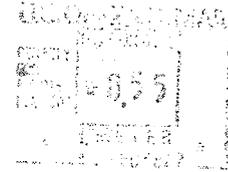
A handwritten signature in black ink, appearing to read "Carl Bausch". The signature is fluid and cursive, with a long horizontal stroke at the end.

Carl Bausch
Deputy Director, Environmental Services
Policy and Program Development

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