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Guidance for Industry

How to Submit a Request for a Meeting or Teleconference in Electronic Format by E-mail

(THIS VERSION OF THE GUIDANCE REPLACES THE VERSION MADE AVAILABLE IN FEBRUARY 2001)

This guidance document is intended to provide instruction on how to submit a request for a meeting or teleconference in electronic format by e-mail to the Office of New Animal Drug Evaluation (ONADE) at the Center for Veterinary Medicine (CVM or the Center).

Comments and suggestions regarding this document should be sent to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. All comments should be identified with the exact title of the document.

For questions regarding this document, contact Margaret Zabriski, Center for Veterinary Medicine (HFV-016), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 301-827-4023, E-mail: margaret.zabriski@fda.gov.

According to the Paperwork Reduction Act of 1995, a collection of information should display a valid OMB control number. The valid OMB control number for this information collection is 0910-0452. The time required to complete this information collection is estimated to vary from 15 minutes to 2 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
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GUIDANCE FOR INDUSTRY[1]

HOW TO SUBMIT A REQUEST FOR A MEETING OR TELECONFERENCE IN ELECTRONIC FORMAT BY E-MAIL

This guidance represents the Agency's current thinking on how to submit a request for a meeting or teleconference in electronic format to the Office of New Animal Drug Evaluation by e-mail. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statue and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance provides advice to industry regarding the procedures to submit a request for a meeting or teleconference in electronic format to the Office of New Animal Drug Evaluation by e-mail.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

Any person intending to file a new animal drug application or abbreviated new animal drug application is entitled to request meetings and/or teleconferences to reach agreement regarding a submission or investigational requirement (21 USC 3606(b)(3)). Every person outside the Federal Government may request a meeting with representative(s) of FDA to discuss a matter (21 CFR 10.65(c)). This guidance document describes the procedures that should be followed by persons who submit a request for a meeting or teleconference to the Office of New Animal Drug Evaluation in electronic format by e-mail. The procedures are designed to ensure compliance with FDA's regulations governing Electronic Records found in 21 CFR Part 11, taking into account CVM's current information technology capability and its ability

[1] This guidance has been prepared by CVM at FDA. For additional copies, access the document on the CVM Home Page (http://www.fda.gov/cvm/default.html), or send a request to the Communications Staff, HFV-12, 7519 Standish Place, Rockville, MD 20855.

to ensure the confidentiality, integrity, security and authentication of data submitted to the Center in electronic format by e-mail.

To submit a request for a meeting or teleconference electronically, the sponsor should use the Request for a Meeting or Teleconference form provided by CVM (FORM FDA 3489[2] OMB No. 0910-0452). The sponsor should enter the data directly into an Adobe® Acrobat® form, attach the Agenda for the meeting, and submit the form to CVM as an Adobe® PDF file (compatible with Adobe® Acrobat® 5.05).[3]

The electronic submission of a request for meeting or teleconference is part of the Center's ongoing initiative to provide a method for paperless submissions.

The meeting and teleconference requests should be submitted by an e-mail message from the sponsor to CVM. For reasons of security and verifying the sender's identity, the sponsor should register each individual participant, including a sponsor coordinator, and all individuals who will be sending submissions by e-mail. CVM will assign an Electronic Submissions System (ESS) password for each participant, as outlined in Guidance for Industry #108 "How to Submit Information in Electronic Format by E-Mail" available at the Center's Guidance Page (http://www.fda.gov/cvm/guidance/published.htm).

CVM intends to accept only PDF forms attached to an email message. A sponsor should attach only one meeting request per e-mail message. The maximum file size for submitting information electronically by e-mail is 50 Megabytes (50 MB). No information should be included in the body of the e-mail message.

Electronic records may be submitted instead of paper records provided the requirements of Part 11 are met (21 CFR 11.2). The procedures in this guidance are designed to provide for a means of electronic submission that meet the requirements of Part 11. If a sponsor does not follow this guidance to submit a meeting request electronically, the sponsor should consult with CVM regarding alternative methods for electronic submission that meet the requirements of Part 11 or submit the request in paper.

II. REQUEST FOR A MEETING OR TELECONFERENCE FORM

A copy of FORM FDA 3489 Request for a Meeting or Teleconference (for use with electronic submissions) is available on the CVM Electronic Submission Page at http://www.fda.gov/cvm/index/esubs/esubstoc.html.

[2] A copy of the form along with instructions for completing it can be found on the CVM Electronic Submissions Project Page, http://www.fda.gov/cvm/index/esubs/esubstoc.html.
[3] FDA use of specific products does not constitute an endorsement of those products.

III. CHECKLIST FOR ELECTRONIC SUBMISSION OF A REQUEST FOR A MEETING OR TELECONFERENCE USING FORM FDA 3489

Note these instructions are for Adobe Acrobat 5.0. Other versions may be different.

A sponsor submitting an electronic request for a meeting or teleconference should create an agenda as a single Portable Document Format (PDF) file. This file will be attached to the FORM FDA 3489. This checklist describes the process sponsors should follow to fill out the form, attach the agenda, and submit the information

1. Open the Meeting Request FORM FDA 3489.
2. Fill in all of the applicable fields of FORM FDA 3489.
3. If the "Multiple Documents" box in A2 is selected, up to 20 documents can be entered into the fields provided. If you are amending a pending meeting request involving multiple documents, then you must enter all of pending documents being amended in the fields provided. If the "Multiple Documents" box is not selected, enter the single document information in A3.
4. Select the "Insert Comments" button to add a PDF file containing any comments regarding the meeting request.
5. Select the "Insert Agenda" to add the PDF file containing the Agenda. The form cannot be successfully validated until an agenda has been attached.
6. Once the form is completed, select the "Validate" button to verify all of the required fields are completed. Those fields that are required will be highlighted and must be completed before the form can be sent to CVM.
7. Select the "Add Password" button to change Document Security
   a) Select "Adobe Standard Security" in the "Document Security" window.
   b) Select the "Change Settings" button.
   c) In the "Specify Password" section select the "Password Required to Open Document" checkbox.
   d) Enter your "Current" Electronic Submissions System (ESS) password in the "User Password" field.
   e) Press "Ok" and save your PDF form to your local system.
8. Select the "Save" button to save all changes in the form.
9. *The "Signature" button is currently disabled on the form*.
10. Once the form is validated and secured, select the "Send to CVM" button.
    a) The form will be automatically addressed to cvmdcu@fda.gov**.** Additional addresses can be added to the addressee and/or the cc block.
    b) The form automatically adds "**MEETING**" as the subject line.
11. If you do not receive an acknowledgment receipt from CVM by the third business day after you have sent the submission, call the Electronic Document Control

Unit at 301-827-8277 to report the problem and find out what happened to your submission.

After review of the agenda and proposed dates, CVM will contact the sponsor to finalize details of the meeting.