

# Guidance for Industry

## How to Submit a Request for a Meeting or Teleconference in Electronic Format to CVM

**(THIS VERSION OF THE GUIDANCE REPLACES THE VERSION MADE AVAILABLE IN JUNE 2007)**

This guidance document is intended to provide instruction on how to submit a request for a meeting or teleconference in electronic format to the Office of New Animal Drug Evaluation (ONADE) at the Center for Veterinary Medicine (CVM or the Center). The guidance was revised to update the phone number for the Electronic Document Control Unit and to replace the web site to submit electronic comments.

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.regulations.gov>. All comments should be identified with the exact title of the document. Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

For questions regarding this document, contact Margaret Zabriski, Center for Veterinary Medicine (HFV-010), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9143, E-mail: [margaret.zabriski@fda.hhs.gov](mailto:margaret.zabriski@fda.hhs.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.

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Veterinary Medicine  
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## GUIDANCE FOR INDUSTRY<sup>1</sup>

### HOW TO SUBMIT A REQUEST FOR A MEETING OR TELECONFERENCE IN ELECTRONIC FORMAT TO CVM

**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. 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 statute 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.

**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. 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 to ensure the

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<sup>1</sup> 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.

## CONTAINS NON-BINDING RECOMMENDATIONS

confidentiality, integrity, security and authentication of data submitted to the Center in electronic format.

To submit a request for a meeting or teleconference electronically, the applicant should use the Request for a Meeting or Teleconference form provided by CVM (FORM FDA 3489<sup>2</sup> OMB No. 0910-0452). The applicant should enter the data directly into an Adobe<sup>®</sup> Acrobat<sup>®</sup> form, attach the Agenda for the meeting, and submit the form to CVM as an Adobe<sup>®</sup> PDF file (compatible with Adobe<sup>®</sup> Acrobat<sup>®</sup> 6.0).<sup>3</sup>

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 the applicant to CVM. For reasons of security and verifying the sender's identity, the applicant should register each individual participant, including a coordinator, and all individuals who will be submitting electronic submissions with the Center as outlined in **Guidance for Industry #108 "How to Submit Information in Electronic Format to CVM using the FDA Electronic Submission Gateway"** available at the Center's Guidance Page (<http://www.fda.gov/cvm/guidance/published.htm>).

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 an applicant does not follow this guidance to submit a meeting request electronically, the applicant 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/esubstoc.html>.

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

An applicant 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 applicants should follow to fill out the form, attach the agenda, and submit the information

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<sup>2</sup> 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/esubstoc.html>.

<sup>3</sup> FDA use of specific products does not constitute an endorsement of those products.

## CONTAINS NON-BINDING RECOMMENDATIONS

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 “*Save*” button to save all changes in the form.
8. Select the “*Signature*” button to digitally sign the form. Once the form is digitally signed, you cannot make any changes because all of the fields will be locked for editing.
9. Follow the steps outlined in **Guidance for Industry #108, Section IV.J – Sending a Submission to FDA CVM using the FDA ESG** to submit your form to CVM.
10. If you do not receive a receipt from CVM by the third business day after you have sent the submission, call the Electronic Document Control Unit at 240-276-8584 to report the problem and find out what happened to your submission.

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