Guidance for Industry

How to Submit a Notice of Claimed Investigational Exemption 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 instructions on how to submit Notices of Claimed Investigational Exemption (NCIE's) in electronic format to the Center for Veterinary Medicine (CVM). 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.

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 0910-0117. The time required to complete this information collection is estimated to vary between 15 minutes and 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 NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION IN ELECTRONIC FORMAT TO CVM

This guidance represents the Agency's current thinking on how to submit a notice of claimed investigational exemption in electronic format to CVM. 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 how to submit a Notice of Claimed Investigational Exemption (NCIE) to the Center for Veterinary Medicine (CVM) in electronic format.

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.

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

This guidance implements provisions of the Government Paperwork Elimination Act, Pub. L. No. 105-277, 112 Stat. 2681 (1998), which requires that executive agencies, by October 21, 2003, provide: (1) for the option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures when practicable.

[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.

II. SUBMITTING AN NCIE IN ELECTRONIC FORMAT

An applicant of an investigational new animal drug is required to submit an NCIE prior to the shipment of a new animal drug for clinical tests in animals (21 CFR 511.1(b)(4)). This guidance document describes the procedures that should be followed by applicants who electronically submit NCIE's. 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 confidentiality, integrity, security and authentication of data submitted to the Center in electronic format.

To submit NCIE's electronically, the applicant should use the NCIE form provided by CVM (FORM FDA 3458[2] OMB No. 0910-0117). The applicant should enter the data directly into an Adobe® Acrobat® form and submit the form to CVM as an Adobe® PDF file (compatible with Adobe® Acrobat® 6.0)[3].

The NCIE's 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 21 CFR 11.2 are met. 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 an NCIE electronically, the applicant should consult with CVM regarding alternative methods for electronic submission that meet the requirements of Part 11 or submit the NCIE's in paper.

III. NCIE REGULATORY COMPLIANCE

Typically, applicants submit time-sensitive information by certified mail so that there is a record verifying the date and name of the individual who received the information at CVM. This record may provide evidence of an applicant's compliance with laws and regulations.

Applicants are required to submit NCIE's (i.e., drug shipment notices) ***prior*** to the shipment of new animal drugs for use in clinical tests in animals (21 CFR 511.1(b)(4)). For an NCIE submitted electronically, the date entered by the applicant in the date field of the form will serve as the date of notification to CVM.

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[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/esubstoc.html.

[3] FDA use of specific products does not constitute an endorsement of those products.

CVM will notify the applicant electronically within two business days of receipt of the electronic NCIE to verify that the information was received.

IV. NCIE FORM

A copy of the FORM FDA 3458 Notice of Claimed Investigational Exemption (for use with electronic submissions) is available on the CVM Electronic Submission Page at http://www.fda.gov/cvm/esubstoc.html.

V. CHECKLIST FOR ELECTRONIC SUBMISSION OF NCIE'S USING FORM FDA 3458

1. Open the NCIE FORM FDA 3458.
2. Fill in all of the applicable fields of NCIE.
3. Select the "*Insert Comments*" button to add a PDF file containing any comments regarding the NCIE, if necessary.
4. 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 digitally signed.
5. Select the "*Save*" button to save all changes in the form.
6. 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.
7. 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.
8. 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.