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Guidance for Industry

Submitting a Notice of Claimed Investigational Exemption in Electronic Format to the Center for Veterinary Medicine via E-Mail

(THIS VERSION OF THE GUIDANCE REPLACES THE VERSION THAT WAS MADE AVAILABLE IN JANUARY 1999)

This guidance document is intended to instruct those who submit Notices of Claimed Investigational Exemption (NCIE's) in electronic format via e-mail to the Center for Veterinary Medicine (CVM).

Comments and suggestions regarding this guidance document should be submitted to the Dockets Management Branch (HFV-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the exact title of the document.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
June 26, 2001

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GUIDANCE FOR INDUSTRY[1]

SUBMITTING A NOTICE OF CLAIMED INVESTIGATIONAL EXEMPTION IN ELECTRONIC FORMAT TO THE CENTER FOR VETERINARY MEDICINE VIA E-MAIL

This guidance represents FDA's current thinking on this matter. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used as long as it satisfies the requirements of the applicable statute and regulations.

I. BACKGROUND

To determine the practicality of electronic submission and review as an alternative to the current paper-based processes, CVM initiated a pilot project that allowed sponsor companies to submit Notices of Claimed Investigational Exemption (NCIE's), often referred to as drug shipment notices, as e-mail attachments via the Internet.[2] NCIE's were selected for the initial pilot because of their simplicity, size, and broad use within CVM and by nearly all sponsors. (See Guidance for Industry #108 entitled How to Use E-Mail to Submit Information to the Center for Veterinary Medicine (CVM), found on the Internet from the CVM Home Page at http://www.fda.gov/cvm for specifications and general instructions on submitting information electronically to CVM via e-mail.)

The pilot began on September 8, 1997, and was conducted for six months, ending on March 9, 1998, with an interim review after three months, on December 8, 1997. The results of the review are provided in a document entitled the Three Month Report[3] (report). The report recommended that the Center "officially adopt the procedures for NCIE electronic submissions."

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[1] This guidance has been prepared by the Center for Veterinary Medicine (CVM) at the Food and Drug Administration. For additional copies of this guidance, access the document on the WWW by connecting to the CVM Home Page at http://www.fda.gov/cvm or send a request to the Communications Staff, HFV-12, 7500 Standish Place, Rockville, MD 20855.

[2] Please note that a **new** investigational file should be established in accordance with current practices, and not by use of the electronic NCIE.

[3] A copy of the Three Month Report can be found on the CVM Home Page at http://www.fda.gov/cvm.

II. REQUIREMENTS TO PARTICIPATE

The requirements set forth in this guidance document are dependent on 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 via e-mail.

For the purposes of submitting electronic NCIE's, the sponsor agrees to use the NCIE form provided by CVM (FORM FDA 3458 (For use with electronic submissions)[4] OMB No. 0910-0117), which will be submitted to CVM as an Adobe® PDF file (compatible with Adobe ®Acrobat® 4.0).[5] The sponsor must be able to either create a word processing document with the necessary data and convert it to a PDF file or enter the data into an Adobe Acrobat form directly.

The NCIE's may be submitted for review by any of the following CVM divisions: Division of Therapeutic Drugs for Non-Food Animals (HFV-110), Division of Biometrics and Production Drugs (HFV-120), Division of Therapeutic Drugs for Food Animals (HFV-130), and/or Division of Animal Feeds (HFV-220).

The NCIE's will be submitted via an Internet e-mail message from the sponsor to CVM. For reasons of security and verifying the sender's identity, the sponsor will register each individual participant with the Center as outlined in Guidance for Industry #108. This includes a sponsor coordinator and all individual contacts who will be sending submissions via e-mail.

The sponsor must agree to attach the NCIE as a PDF file to the e-mail message. Only one PDF attachment per e-mail message will be permitted. The maximum file size for submitting information electronically via e-mail is 1 Megabyte (1 MB). No information should be included in the body of the e-mail message.

The sponsor must agree to use a standardized convention for the subject line of each e-mail transmission. The sponsor will type in the four characters, **NCIE**, in capital letters, no quotation marks, and no other words in the subject line.

These requirements must be met for CVM to accept NCIE's electronically as the official copy, in lieu of paper, as allowed by 21 CFR 11. If sponsors are not capable of meeting these requirements, then they must submit the NCIE's in paper.

[4] A copy of the form along with instructions for completing it can be found on the CVM Home Page, http://www.fda.gov/cvm.

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

III. NCIE REGULATORY COMPLIANCE

Typically, time-sensitive information is submitted via certified mail so that the sponsor has a record verifying the date and name of individual who received the information at CVM. This also provides a legal basis by which sponsors can assert their compliance with laws and regulations.

For NCIE's, sponsors are required to submit their drug shipment notices ***prior*** to the shipment of new animal drugs for use in clinical animals as required by 21 CFR 511.1(b)(4). Currently, CVM reviews the date on the cover letter of paper NCIE to determine whether notification was made prior to delivery. For an electronic NCIE, the date field entered by the sponsor within the form will serve as the date of notification to CVM. As a means of verifying that the information was received, CVM should respond with an e-mail message back to the sponsor within two business days of receipt of the electronic NCIE.

IV. ERROR REPORTING AND EVALUATION

For purposes of the NCIE electronic submission project, sponsors need only report to CVM exceptions to normal processing at the time they occur. An example of an exception would be not receiving an acknowledgment from CVM within two business days (see Guidance for Industry #108 for details). If an electronic acknowledgment has not been received from CVM by the third business day after the sponsor sent the electronic submission, the sponsor should contact CVM. Any such problems or errors should be reported by telephone to CVM's Electronic Document Control Unit (301-827-8277).

Direct all other comments, questions on the instructions, and suggestions for future electronic submission projects to the Project Coordinator, Ms. E. L. Parbuoni (301-827-4621).

These comments will help determine the future direction for electronic submissions within the Center. CVM should continue to monitor and evaluate electronic submission initiatives and make recommendations for improvement that will be incorporated into future guidance documents regarding electronic submissions.

V. CHECKLIST FOR NCIE PROCESS USING WORD PROCESSING FORM

This checklist describes a process for creating a PDF file using a word processing form and printing it to the Acrobat ®Distiller. The PDF file may be created by other means.

1. Open blank NCIE form in word processing package.
2. Make sure Acrobat® Distiller is selected as the default printer.
3. Fill in all pertinent sections of NCIE.
4. Print the word processing document to Acrobat ®Distiller to create a PDF file.
5. Name the PDF file using an 8.3 file naming conventions. Save the PDF file in the appropriate directory location and close the file.
6. Open the PDF file in Adobe® Acrobat®4.0 select "Save As" and select the "Security" options for "Specify Password To: Open the Document". Enter your password and click OK. Verify the password by entering it again and then "Save" the PDF file.
7. Open e-mail and begin a new message.
8. Address it to **cvmdcu@cvm.fda.gov.**
9. Type **NCIE** in the subject line, all capital letters, no other punctuation or information.
10. Do not type anything in the body of the message.
11. Attach the PDF file of the NCIE to the e-mail message.
12. Send the e-mail message.
13. If you do not receive an acknowledgment receipt from CVM (stars@cvm.fda.gov) 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.

VI. NCIE FORM

A copy of the NCIE form, FORM FDA 3458 (For use with electronic submissions), is available on the CVM Home Page at http://www.fda.gov/.

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Supervisory Interdisciplinary Scientist, GS-*-15
(401- Biologist, 403-Microbiologist, 405- Pharmacologist, 415-Physiologist, 1320-Chemist, 701- Veterinary Medical Officer)
Closing Date: October 31, 2002

Interdisciplinary Scientist, GS-*-14
(487- Animal Scientist, 701- Veterinary Medical Officer, 1320-Chemist,)
Closing Date: October 31, 2002

Hot Topic

Protecting Pets from Mosquito-Borne Diseases

More About What's New in CVM ...

CVM Updates - are issued by the Center for Veterinary Medicine

FDA Veterinarian - This newsletter is published bimonthly.

Updated Thursday, October 3, 2002 at 10: 16 AM ET

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