

Guidance for Industry

How to Submit a Notice of Intent to Slaughter for Human Food Purposes 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 instructions on how to submit a notice of intent to slaughter for human food purposes in electronic format by e-mail to 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 0910-0450. The time required to complete this information collection is estimated to vary between 15 minutes to 1 hour 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 INDUSTRY¹

HOW TO SUBMIT A NOTICE OF INTENT TO SLAUGHTER FOR HUMAN FOOD PURPOSES IN ELECTRONIC FORMAT BY E-MAIL

This guidance represents the Agency's current thinking on how to submit a notice of intent to slaughter for human food purposes in electronic format 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 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 Notice of Intent to Slaughter for Human Food Purposes in electronic format by e-mail to the Center for Veterinary Medicine (CVM).

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.

Section 512(j) of the Federal Food, Drug, and Cosmetic Act gives FDA the authority to issue regulations that set out the conditions on which investigational animals may be marketed for food-use. FDA's regulations 21 CFR 511.1(b)(4) provide that sponsors must obtain authorization to use the edible products derived from investigational food-producing animals for food. Under 21 CFR 511.1(b)(5), CVM may issue an authorization letter permitting a new animal drug sponsor (sponsor) to use edible products from investigational animals under specific conditions. USDA also monitors the slaughter of animals treated with investigational new animal drugs under the authority of the Meat Inspection Act, 21 USC 601-95. To assist CVM and

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.

CONTAINS NON-BINDING RECOMMENDATIONS

USDA with this monitoring, the authorization letter states that sponsors must submit slaughter notices each time such animals are to be slaughtered unless this notice is waived in the authorization letter. This guidance will give sponsors the option to submit a slaughter notice as an e-mail attachment to CVM.

The electronic submission of slaughter notices 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.

To electronically submit a slaughter notice, the sponsor should use the Notice of Intent to Slaughter for Human Food Purposes form provided by CVM (FORM FDA 3488² OMB No. 0910-0450) the sponsor 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[®] 5.05).³

The form should be submitted by 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, with the Center 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 submitted as attachments to an e-mail message. A sponsor should attach only one PDF attachment 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 they meet the requirements of 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 Notice of Intent to Slaughter for Human Food Purposes electronically, the sponsor should consult with CVM regarding alternative methods for electronic submission that meet the requirements of Part 11 or submit the slaughter notice in paper.

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.

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II. NOTICE OF INTENT TO SLAUGHTER FOR HUMAN FOOD PURPOSES FORM

A copy of FORM FDA 3488 Notice of Intent to Slaughter for Human Food Purposes (for use with electronic submissions) is available on the CVM Electronic Submission Page at <http://www.fda.gov/cvm/index/esubs/esubstoc.html>.

III. CHECKLIST FOR ELECTRONIC SUBMISSION OF A NOTICE OF INTENT TO SLAUGHTER FOR HUMAN FOOD PURPOSES USING FORM FDA 3488

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

1. Open the Intent to Slaughter FORM FDA 3488.
2. Fill in all pertinent sections of FORM FDA 3488.
3. Select the “Insert Comments” button to add a PDF file containing any comments regarding the form.
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 sent to CVM.
5. 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.
6. Select “Save” to save all information on the form.
7. *The “Signature” button is currently disabled on the form.*
8. Once the form is validated and secured, select the “Send to CVM” button.
 - a. The form will be automatically addressed to cvmdu@fda.gov. Additional addresses can be added to the addressee and/or the cc block.
 - b. The form automatically adds “**SLAUGHTER**” as the subject line.
9. 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.

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Sponsors are requested to submit their slaughter notification to FDA and USDA **at least 10 days prior** to shipment for slaughter unless conditions outlined in the authorization letter waived this requirement.