§ 1401.605 How are violations of this part determined for recipients who are individuals?

An individual recipient is in violation of the requirements of this part if the Director, PAM determines, in writing, that—

(a) The recipient has violated the requirements of subpart C of this part; or

(b) The recipient is convicted of a criminal drug offense resulting from a violation occurring during the conduct of any award activity.

§ 1401.610 What actions will the Federal Government take against a recipient determined to have violated this part?

If a recipient is determined to have violated this part, as described in §1401.600 or §1401.605, DOI may take one or more of the following actions—

(a) Suspension of payments under the award;

(b) Suspension or termination of the award; and

(c) Suspension or debarment of the recipient under 2 CFR part 180, for a period not to exceed five years.

§ 1401.615 Are there any exceptions to those actions?

The Secretary of the Interior may waive with respect to a particular award, in writing, a suspension of payments under an award, suspension or termination of an award, or suspension or debarment of a recipient if the Secretary of the Interior determines that such a waiver would be in the public interest. This exception authority cannot be delegated to any other official.

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

12 CFR Part 1101

[FFIEC–2010–0002]

Description of Office, Procedures, and Public Information

AGENCY: Federal Financial Institutions Examination Council.
In 12 CFR 1101.4(b)(2), the Council revises the heading to reflect current FOIA terminology concerning discretionary releases of exempt information.

In 12 CFR 1101.4(b)(3)(i), the Council revises the paragraph to provide the current address of the Council’s offices, to allow the submission of FOIA requests by facsimile and e-mail, and to require that requests reasonably describe the records sought.

In 12 CFR 1101.4(b)(3)(ii) the Council revises the paragraph to specify the information that a request must contain in order to be considered a “proper FOIA request” (i.e., a request to which a response is required). In addition, the Council revises the paragraph to require a requester to identify whether the information sought by a FOIA request is requested for commercial use, and whether the requester is an educational or noncommercial scientific institution, or news media representative, and to address the payment of fees.

In 12 CFR 1101.4(b)(3)(iii), the Council modifies the language of the paragraph to clarify that the Council need not accept or process a defective FOIA request, and to provide that such a request may be returned to the requester specifying the deficiency.

In 12 CFR 1101.4(b)(3)(iv), the Council adds a procedure to request the expedited treatment of FOIA requests. A requester seeking to have the processing of a request expedited must show a compelling need for expedited processing.

In 12 CFR 1101.4(b)(3)(v), the Council revises its procedures to increase the time limit in which the Council must respond to a FOIA request from 10 working days to 20 working days in accordance with the Electronic Freedom of Information Act Amendments, and to clarify what information the Council’s response to a FOIA request must contain.

In 12 CFR 1101.4(b)(3)(vi), the Council revises the paragraph to shorten the time period in which an administrative appeal of a denied request may be brought from 35 calendar days to 10 working days, to provide for the filing of administrative appeals by facsimile, and to update the mailing address of the Council.

In 12 CFR 1101.4(b)(3)(vii), the Council revises the paragraph to clarify that the time in which the Council has to respond to an appeal runs from the actual receipt of the appeal by the Executive Secretary of the Council.

In 12 CFR 1101.4(b)(4)(i), the Council designates the existing paragraph, 12 CFR 1101.4(b)(4), as paragraph 1101.4(b)(4)(i), and makes a minor grammatical change to the language of the paragraph.

The Council adds 12 CFR 1101.4(b)(4)(ii), which provides that if the responsive records are to be delivered to the requester, they will be mailed to the requester unless the Executive Secretary of the Council determines that it is appropriate to send the records by some other means.

The Council adds 12 CFR 1101.4(b)(4)(iii), which indicates that the Council will provide a copy of a responsive record in the format requested by the requester if the record is “readily reproducible” in that format.

The Council adds 12 CFR 1101.4(b)(4)(iv) to permit records to be provided electronically, and to provide that if the information is subject to the Privacy Act, 5 U.S.C. 552a, it will not be sent electronically unless “reasonable security measures” can be established.

In 12 CFR 1101.4(b)(5)(i)(C), the Council revises the definition of the term “Duplication” to provide examples of the forms of document reproduction that may be used by the Council.

In 12 CFR 1101.4(b)(5)(i)(D), the Council makes a minor change to the wording of the paragraph replacing the character “§” with the word “section.”

In 12 CFR 1101.4(b)(5)(i)(E), the Council adds a provision to allow the Executive Secretary of the Council to consider the use to which the requester will put the records, and to seek additional information on the use, if necessary, in order to determine whether a particular FOIA request is a “commercial” one.

In 12 CFR 1101.4(b)(5)(i)(G), the Council makes a minor change to the wording of the paragraph replacing the character “§” with the word “section.”

In 12 CFR 1101.4(b)(5)(i)(H), the Council revises its definition of “Representative of the news media” to reflect the definition provided in the OPEN Government Act, 5 U.S.C. 552(a)(4)(A)(i).

In 12 CFR 1101.4(b)(5)(ii)(C), the Council makes a minor change to the wording of the paragraph replacing the character “§” with the word “section.”

In 12 CFR 1101.4(b)(5)(ii)(G), the Council makes a minor change to the wording of the paragraph replacing the character “§” with the word “section.”

In 12 CFR 1101.4(b)(5)(ii)(H), the Council revises the procedures for requesting a waiver or reduction of fees. The revisions include eliminating the list of factors that may be considered by the Council in determining whether the public interest requirement is met, requiring a requester to state a justification for a waiver or reduction of fees, and providing a right to administratively appeal the denial of a request for a waiver or reduction of fees.

In 12 CFR 101.4(b)(5)(iii), the Council makes a minor grammatical change to the language of the paragraph.

In 12 CFR 101.4(b)(5)(iv), the Council makes a minor change to the statutory citation contained in the paragraph.

In 12 CFR 1101.4(b)(5)(v)(B), the Council makes a minor change to the wording of the paragraph replacing the character “§” with the word “section,” and by increasing the limit stated in the parenthetical phrase to 20 working days in accordance with subsection (a)(6) of the FOIA, 5 U.S.C. 552(a)(6).

In 12 CFR 1101.4(b)(6), the Council revises the paragraph to provide that referral or consultation with another agency is appropriate whenever the requested record originated with, or incorporates the information of, another state or federal agency.

III. Analysis of Comments Received

The Council received no comments on the proposed rules.

IV. Regulatory Analysis and Procedure

A. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601, et seq.) (RFA), the Council certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The final rule addresses only the procedures to be followed to request records of the Council. Small entities, like any other individual or entity, may request information from the Council pursuant to the FOIA that has not been generally made available to the public. Under the FOIA, agencies may recover only the direct costs of searching for, reviewing, and duplicating the records processed for certain categories of requesters. The Council’s fee structure is in accordance with Department of Justice and Office of Management and Budget (OMB) guidelines, and is based upon the category of requester. Thus, fees assessed by the Council are nominal and will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

B. Paperwork Reduction Act

The Council has determined that the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., does not apply because these rules do not impose any new information collection requirements that require the approval of the OMB.

The Council has determined that the final rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, enacted as part of the Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999 (Pub. L. 105–277, 112 Stat. 2681).

D. Small Business Regulatory Enforcement Fairness Act

OMB has determined that the rule is not a “major rule” within the meaning of the relevant sections of the Small Business Regulatory Enforcement Act of 1996 (5 U.S.C. 301 et seq.). As required by SBREFA, the Council will file the appropriate reports with Congress and the General Accounting Office so that the rule may be reviewed.

E. Solicitation of Comments on Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act, Public Law 106–102, 113 Stat. 1338, 1471 (Nov. 12, 1999), requires the federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The Council received no comment on plain language. Nevertheless, the Council has sought to present the final rule in a simple, comprehensible, and straightforward manner.

Lists of Subjects in 12 CFR Part 1101

Freedom of information, FOIA exemptions, Schedule of fees, Waivers or reductions of fees.

For the reasons set forth in the preamble, the Council amends 12 CFR part 1101 as follows:

PART 1101—DESCRIPTION OF OFFICE, PROCEDURE, PUBLIC INFORMATION

1. The authority citation for part 1101 continues to read as follows:


2. Section 1101.3 is amended by revising paragraph (e) to read as follows:

§ 1101.3 Organization and methods of operation.

(e) Council address. Council offices are located at 3501 Fairfax Drive, Room B–7081a, Arlington, VA, 22226–3550.

3. Section 1101.4 is amended:

a. By revising paragraph (a);

b. By revising the heading for paragraph (b) and paragraphs (b)(1)

introductory text, (b)(1)(i), (v), (vii), and (viii);

c. By revising paragraphs (b)(2), (3), and (4);

d. By revising paragraphs (b)(5)(i)(C), (D), (E), (G), and (H) and (b)(5)(ii)(C)(2), (F), and (H);

and

e. By revising paragraphs (b)(5)(iii)(A), (b)(5)(iv), (b)(5)(vii)(B), (C), and (b)(6).

The revisions read as follows:

§ 1101.4 Disclosure of information, policies, and records.

(a) Statements of policy published in the Federal Register or available for public inspection and copying; indices. Under 5 U.S.C. 552(a)(1), the Council publishes general rules, policies and interpretations in the Federal Register. Under 5 U.S.C. 552(a)(2), policies and interpretations adopted by the Council, including instructions to Council staff affecting members of the public, and an index to the same, are available for public inspection and copying at the office of the Executive Secretary of the Council, 3501 Fairfax Drive, Room B–7081a, Arlington, VA, 22226–3550, during regular business hours. Policies and interpretations of the Council may be withheld from disclosure under the principles stated in paragraph (b)(1) of this section.

(b) Other records of the Council available to the public upon request; procedures—(1) General rule and exemptions. Under 5 U.S.C. 552(a)(3), all other records of the Council are available to the public upon request, except to the extent exempted from disclosure as provided in this paragraph (b). Except as specifically authorized by the Council, the following records, and portions thereof, are not available to the public: (i) A record, or portion thereof, which is specifically authorized under criteria established by an Executive Order to be kept secret in the interest of national defense or foreign policy and which is, in fact, properly classified information; (ii) any intra-agency or interagency memorandum or letter that would not be routinely available by law to a private party in litigation, including, but not limited to, memoranda, reports, and other documents prepared by the personnel of the Council or its constituent agencies, and records of deliberations of the Council and discussions of meetings of the Council, any Council Committee, or Council staff, that are not subject to 5 U.S.C. 552b (the Government in the Sunshine Act).

(vii) Records or information compiled for law enforcement purposes, to the extent permitted under 5 U.S.C. 552b(7), including records relating to a proceeding by a financial institution’s state or federal regulatory agency for the issuance of a cease-and-desist order, or order of suspension or removal, or assessment of a civil money penalty and the granting, withholding, or revocation of any approval, permission, or authority. (viii) A record, or portion thereof, containing, relating to, or derived from an examination, operating, or condition report prepared by, or on behalf of, or for the use of any state or federal agency directly or indirectly responsible for the regulation or supervision of financial institutions.

(2) Discretionary release of exempt information. Notwithstanding the applicability of an exemption, the Council or the Council’s designee may elect, under the circumstances of a particular request, to disclose all or a portion of any requested record where permitted by law. Such disclosure has no precedential significance.

(3) Procedure for records request—(i) Initial request. Requests for records shall be submitted in writing to the Executive Secretary of the Council: (A) By sending a letter to: FFIEC, Attn: Executive Secretary, 3501 Fairfax Drive, Room B–7081a, Arlington, VA 22226–3550. Both the mailing envelope and the request should be marked “Freedom of Information Request,” “FOIA Request,” or the like; or (B) By facsimile clearly marked “Freedom of Information Act Request,” “FOIA Request,” or the like to the Executive Secretary at (703) 562–6446; or

(C) By e-mail to the address provided on the FFIEC’s World Wide Web page, found at: http://www.ffiec.gov. Requests must reasonably describe the records sought.

(ii) Contents of request. All requests should contain the following information: (A) The name and mailing address of the requester, an electronic mail address, if available, and the telephone number at which the requester may be reached during normal business hours; (B) A statement as to whether the information is intended for commercial use, and whether the requester is an educational or noncommercial scientific institution, or news media representative; (C) A statement agreeing to pay all applicable fees, or a statement identifying any desired fee limitation, or a request for a waiver or reduction of fees that satisfies paragraph (b)(5)(ii)(H) of this section.
(iii) Defective requests. The Council need not accept or process a request that does not reasonably describe the records requested or that does not otherwise comply with the requirements of this section. The Executive Secretary may return a defective request specifying the deficiency. The requester may submit a corrected request, which will be treated as an initial request.

(iv) Expedited processing. (A) Where a person requesting expedited access to records has demonstrated a compelling need for the records, or where the Executive Secretary has determined to expedite the response, the Executive Secretary shall process the request as soon as practicable. To show a compelling need for expedited processing, the requester shall provide a statement demonstrating that:

1. Failure to obtain the records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual; or
2. The requester is primarily engaged in information dissemination as a main professional occupation or activity, and there is urgency to inform the public of the government activity involved in the request.

(B) The requester’s statement must be certified to be true and correct to the best of the person’s knowledge and belief and explain in detail the basis for requesting expedited processing.

(C) The formality of the certification required to obtain expedited treatment may be waived by the Executive Secretary as a matter of administrative discretion.

(v) Response to initial requests. (A) Except where the Executive Secretary has determined to expedite the processing of a request, the Executive Secretary will respond by mail or electronic mail to all properly submitted initial requests within 20 working days of receipt. The time for response may be extended up to 10 additional working days, as provided in 5 U.S.C. 552(a)(6)(B), or for other periods by agreement between the requester and the Executive Secretary.

(B) In response to a request that reasonably describes the records sought and otherwise satisfies the requirements of this section, a search shall be conducted of records in existence and maintained by the Council on the date of receipt of the request, and a review made of any responsive information located. The Executive Secretary shall notify the requester of:

1. The Executive Secretary’s determination of the response to the request;
2. The reasons for the determination;
3. If the response is a denial of an initial request or if any information is withheld, the Executive Secretary will advise the requester in writing:
   1. If the denial is in part or in whole;
   2. The name and title of each person responsible for the denial (when other than the person signing the notification);
   3. The exemptions relied on for the denial; and
4. The right of the requester to appeal the denial to the Chairman of the Council within 10 working days following the date of issuance of the notification, as specified in paragraph (b)(3)(vi) of this section.

(vi) Appeals of responses to initial requests. If a request is denied in whole or in part, the requester may appeal in writing, within 10 working days of the date of issuance of a denial determination. Appeals shall be submitted to the Chairman of the Council: (A) By sending a letter to: FFIEC, Attn: Executive Secretary, 3501 Fairfax Drive, Room B–7081a, Arlington, VA, 22226–3550. Both the mailing envelope and the request should be marked “Freedom of Information Act Appeal,” “FOIA Appeal,” or the like; or (B) By facsimile clearly marked “Freedom of Information Act Appeal,” “FOIA Appeal,” or the like to the Executive Secretary at (703) 562–6446. Appeals should refer to the date and tracking number of the original request and the date of the Council’s initial ruling. Appeals should include an explanation of the basis for the appeal.

(vii) Council response to appeals. The Chairman of the Council, or another member designated by the Chairman, will respond to all properly submitted appeals within 20 working days of actual receipt of the appeal by the Executive Secretary. The time for response may be extended up to 10 additional working days, as provided in 5 U.S.C. 552(a)(6)(B), or for other periods by agreement between the requester and the Chairman or the Chairman’s designee.

(4) Procedure for access to records if request is granted. (i) When a request for access to records is granted, in whole or in part, a copy of the records to be disclosed will be promptly delivered to the requester or made available for inspection, whichever was requested. Inspection of records, or duplication and delivery of copies of records will be arranged so as not to interfere with their use by the Council and other users of the records.

(ii) When delivery to the requester is to be made, copies of requested records shall be sent to the requester by regular U.S. mail to the address indicated in the request, unless the Executive Secretary deems it appropriate to send the documents by another means.

(iii) The Council shall provide a copy of the record in any form or format requested if the record is readily reproducible by the Council in that form or format, but the Council need not provide more than one copy of any record to a requester.

(iv) By arrangement with the requester, the Executive Secretary may elect to send the responsive records electronically if a substantial portion of the records is in electronic format. If the information requested is subject to disclosure under the Privacy Act of 1974, 5 U.S.C. 552a, it will not be sent by electronic means unless reasonable security measures can be established.

(C) Duplication means the process of making a copy of a document necessary to respond to a FOIA request. Such copies can take the form of paper copy, microfilm, audiovisual records, or machine readable records (e.g., magnetic tape or computer disk).

(D) Review means the process of examining documents located in response to a request that is for a commercial use (see paragraph (b)(5)(i)(E) of this section) to determine whether any portion of any document located is permitted to be withheld and processing such documents for disclosure.

(E) Commercial use request means a request from or on behalf of one who seeks information for a use or purpose that furthers the commercial, trade, or profit interests of the requester or the person on whose behalf the request is made. In determining whether a request falls within this category, the Executive Secretary will determine the use to which a requester will put the records requested and seek additional information as the Executive Secretary deems necessary.

(C) Noncommercial scientific institution means an institution that is not operated on a “commercial” basis as that term is referenced in paragraph (b)(5)(i)(E) of this section, and which is operated solely for the purposes of conducting scientific research, the results of which are not intended to promote any particular product or industry.

(H) Representative of the news media means any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a
distinct work, and distributes that work to an audience. In this clause, the term “news” means information that is about current events or that would be of current interest to the public. Examples of news-media entities are television or radio stations broadcasting to the public at large and publishers of periodicals (but only if such entities qualify as disseminators of “news”) who make their products available for purchase by or subscription by or free distribution to the general public. These examples are not all-inclusive. Moreover, as methods of news delivery evolve (for example, the adoption of the electronic dissemination of newspapers through telecommunications services), such alternative media shall be considered to be news-media entities. A freelance journalist shall be regarded as working for a news-media entity if the journalist can demonstrate a solid basis for expecting publication through that entity, whether or not the journalist is actually employed by the entity. A publication contract would present a solid basis for such an expectation; the Council may also consider the past publication record of the requester in making such a determination.

Waiving or reducing fees. As part of the initial request for records, a requester may ask that the Council waive or reduce fees if disclosure of the records is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Council and is not primarily in the commercial interest of the requester. The initial request for records must also state the justification for a waiver or reduction of fees. Determinations as to a waiver or reduction of fees will be made by the Executive Secretary of the Council and the requester will be notified in writing of his/her determination. A determination not to grant a request for a waiver or reduction of fees under this paragraph may be appealed to the Chairman of the Council pursuant to the procedure set forth in paragraph (b)(3)(vi) of this section.

Categories of requesters. (A) Commercial use requesters. The Council will assess fees for commercial use requesters sufficient to recover the full direct costs of searching for, reviewing for release, the duplicating the records sought.

(iv) Interest on unpaid fees. The Council may begin assessing interest charges on an unpaid bill starting on the 31st day following the day on which the bill was sent. Interest will be at the rate prescribed in 31 U.S.C. 3717 and will accrue from the date of the billing.

(B) A requester has previously failed to pay a fee charged in a timely fashion. The Council may require the requester to pay the full amount owed plus any applicable interest as provided in paragraph (b)(5)(iv) of this section or demonstrate that he/she has, in fact, paid the fee, and to make an advance payment of the full amount of the estimated fee before the Council begins to process a new request or a pending request from that requester.

When the Council acts under paragraph (b)(5)(vi) of this section, the administrative time limits prescribed in subsection (a)(6) of the FOIA (i.e., 20 working days from receipt of initial requests, plus permissible extensions of these time limits) will begin only after the Council has received the fee payments described.

Records of another agency. If a requested record originated with or incorporates the information of another state or federal agency or department, upon receipt of a request for the record the Council will promptly inform the requester of this circumstance and immediately shall forward the request to the originating agency or department either for processing in accordance with the latter’s regulations or for guidance with respect to disposition.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 526

[Docket No. FDA–2010–N–0002]

Intramammary Dosage Form New Animal Drugs; Cloxacillin Benzathine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplementary new animal drug application (NADA) filed by Boehringer Ingelheim Vetmedica, Inc. The supplement provides for minor revisions to labeling.

DATES: This rule is effective November 22, 2010.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteil, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: cindy.burnsteil@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002 has filed a supplement to NADA 55–058 for DRY-CLOX (cloxacillin benzathine) Intramammary Infusion for dry dairy cattle. The supplemental NADA provides for various minor revisions to labeling. The supplemental application is approved as of October 21, 2010, and the regulations in §526.464a (21 CFR 526.464a) are amended to reflect the approval.

In addition, FDA has noticed that certain portions of §526.464a were inadvertently removed when the regulations were amended to reflect a change of sponsorship (75 FR 10165, March 5, 2010). At this time, the regulations are being amended to reflect fully the approved conditions of use of this new animal drug product. This change is being made to improve the accuracy of the animal drug regulations.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required. The Agency has determined under 21 CFR 25.33 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment...