

categories of products shall be handled as set forth in paragraph (c) of this section:

- (1) Therapeutic DNA plasmid products;
- (2) Therapeutic synthetic peptide products of 40 or fewer amino acids;
- (3) Monoclonal antibody products for in vivo use; and
- (4) Therapeutic recombinant DNA-derived products.

* * * * *

(c)(1) To obtain marketing approval for a therapeutic DNA plasmid product, therapeutic synthetic peptide product of 40 or fewer amino acids, monoclonal antibody product for in vivo use, or therapeutic recombinant DNA-derived product, an applicant shall submit to the Director, Center for Biologics Evaluation and Research, a biologics license application on a form prescribed by the Director, Center for Biologics Evaluation and Research. For such products, a separate establishment license application shall not be required. An application for a license for such a product shall include:

(i) Data derived from nonclinical laboratory and clinical studies that demonstrate that the manufactured product meets prescribed standards of safety, purity, and potency; with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in part 58 of this chapter, or,

(ii) If the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance;

(iii) Statements regarding each clinical investigation involving human subjects contained in the application, that it either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with §§ 56.104 or 56.105 of this chapter, and was conducted in compliance with requirements for informed consent set forth in part 50 of this chapter;

(iv) A full description of manufacturing methods;

(v) Data establishing stability of the product through the dating period;

(vi) Sample(s) representative of the product to be sold, bartered, or exchanged or offered, sent, carried or brought for sale, barter, or exchange;

(vii) Summaries of results of tests performed on the lot(s) represented by the submitted samples; and

(viii) Specimens of the labels, enclosures, and containers proposed to be used for the product.

(2) An application for license shall not be considered as filed until all pertinent information and data have been received from the applicant by the Center for Biologics Evaluation and Research. The applicant shall also include either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

(3) Approval of the biologics license application and issuance of the biologics license shall constitute a determination that the establishment and the product meet applicable standards established in this chapter to ensure the continued safety, purity, and potency of such products. Applicable standards for the maintenance of establishments for the manufacture of a product subject to this paragraph (c) shall include the good manufacturing practice requirements set forth in parts 210 and 211 of this chapter. The following sections in parts 600 through 680 of this chapter shall not be applicable to such products: §§ 600.10(b) and (c), 600.11, 600.12, 600.13, 601.1, 601.30, 601.31, 601.32, 610.11, 610.53, and 610.62 of this chapter.

(4) The term "product license application," as it is used in those sections of parts 600 through 680 of this chapter that are applicable to products subject to this paragraph (c) shall include a biologics license application for a therapeutic DNA plasmid product, therapeutic synthetic peptide product of 40 or fewer amino acids, monoclonal antibody product for in vivo use, or therapeutic recombinant DNA-derived product.

(5) To the extent that the requirements in this paragraph (c) conflict with other requirements in this subchapter, this paragraph (c) shall supersede such other requirements.

5. Section 601.22 is amended by adding a sentence after the second sentence to read as follows:

§ 601.22 Products in short supply; initial manufacturing at other than licensed establishment.

* * * For persons and places authorized under this section to conduct the initial and partial manufacturing of a product for shipment solely to a manufacturer of a product subject to licensure under § 601.2(c), the following additional regulations shall not be applicable: §§ 600.10(b) and (c), 600.11, 600.12, 600.13, 610.11, and 610.53 of this chapter * * *.

Dated: May 6, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96-12144 Filed 5-10-96; 10:13 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Coast Guard

33 CFR Part 52

[OST Docket No. OST-95-878]

RIN 2105-AC31

Coast Guard Board for Correction of Military Records; Procedural Regulation

AGENCY: Office of the Secretary, Coast Guard, DOT.

ACTION: Final Rule.

SUMMARY: The Department is amending its regulation with respect to reconsideration of final decisions of the Board for Correction of Military Records of the Coast Guard (BCMR). This action is taken on the Department's initiative in order to streamline processing of these cases and to clarify the circumstances under which final decisions can be reconsidered. The amendment will make it possible for the BCMR to expedite the processing of reconsideration requests and it will increase the resources available to meet the requirement that all cases be decided within 10 months of the receipt of a completed application.

EFFECTIVE DATE: June 13, 1996.

FOR FURTHER INFORMATION CONTACT: Robert H. Joost, Chairman, Board for Correction of Military Records of the Coast Guard, C-60, Office of the General Counsel, U.S. Department of Transportation, 400 Seventh Street, SW, Washington, D.C. 20590-0001. Telephone: (202) 366-9335.

SUPPLEMENTARY INFORMATION:

Comments on Proposed Rulemaking

Proposed rulemaking was published on pages 63489-63491 of the Federal Register of December 11, 1995 [60 FR 63489], and invited comments for 60 days ending February 9, 1996. Comments were received from the following sources: (1) Eugene R. Fidell, Esq., an attorney in private practice; and (2) Michael J. Calabro, Esq., an attorney in private practice. The comments and the actions taken in response to the comments are summarized below.

Both attorneys expressed concern with respect to the amount of time that

may be consumed in processing a reconsideration request. The BCMR appreciates this concern, but believes that delay, which is a problem in the current reconsideration process, would be significantly reduced under the proposed rule. The proposed rule, by eliminating duplicative review of a reconsideration application, as required by the current § 52.67(c), and by providing for an expedited process in handling facially defective reconsideration requests, will require less time per reconsideration request than the current rule.

One of the commenting attorneys questioned the authority given to the Chairman in proposed § 52.67(b) on the ground that the enabling statute (10 U.S.C. § 1552) requires BCMR decisions to be made by the Secretary acting through a board. That is true, but it is only true with respect to an original decision. Section 1552 of title 10 does not provide for, nor does it prohibit, the reconsideration of original decisions. Reconsideration authority has been added by the BCMR's regulations and its parameters can therefore be determined by those regulations.

Comments were also offered on other aspects of the correction board process for the Coast Guard. One attorney asked that the BCMR's basic time limit regulation be updated, even though that was not a subject addressed in the proposed rule. Both attorneys made suggestions with regard to administrative matters that do not bear on the proposed rule and do not require a rules change to implement: appropriate designations and numbering for docketed reconsideration requests; the formalization and publication of the Secretary's delegate's authority; improvement of the system for indexing and retrieval of redacted Coast Guard BCMR decisions; availability of redacted decisions to all who are interested by bulletin board, CD-ROM, or mailed to subscribers on a mailing list, in return for a reasonable fee. None of these comments bear on the reconsideration regulation that is being considered in this rulemaking process. Therefore, while these matters remain under consideration, they are not addressed at this time.

Final Rule

This final rule explicitly authorizes the Board to consider applications for reconsideration upon a showing that the Board committed legal or factual error in the original determination that could have resulted in a determination other than that made.

This final rule also authorizes the Chairman not to docket applications for

reconsideration that do not meet the threshold requirements for reconsideration, i.e., applications that only (1) present evidence or information previously considered by the Board, (2) present new evidence or information that is clearly not material to the result in the case, (3) present new evidence or information that could have been submitted earlier with the exercise of reasonable diligence, or (4) make arguments as to legal or factual error that are clearly not material to the result. The phrase "otherwise comes to the attention of the Board" has been deleted, however, as unnecessary.

This final rule also provides that no Board member who considered an applicant's original application for correction would participate in the consideration of that person's application for reconsideration. There will, to the extent practicable, be a related prohibition on the staff member; the person who drafted the original decision would not draft the reconsideration decision. In light of these safeguards, it would not be necessary for the Secretary's designate to approve each denial of a reconsideration request, thus expediting the review process.

Section-by-Section Analysis

Section 52.67, Reconsideration, is rewritten to add the new requirements outlined above, and to simplify the procedure on reconsideration.

Paragraph (a) provides that reconsideration of an application may occur if the applicant meets at least one of two sets of criteria. The first of these, paragraph (a)(1), directs reconsideration if an applicant presents evidence or information that was not previously considered by the Board if that evidence or information could result in a different determination and if it "could not have been presented to the Board prior to its original determination if the applicant had exercised reasonable diligence." The second of these, paragraph (a)(2), directs reconsideration if an applicant presents evidence or information that the Board committed legal or factual error in the original determination that could have resulted in a different result.

Paragraph (b) directs the Chairman to docket a reconsideration request if it meets the requirements of paragraph (a)(1) or (a)(2). If neither of these requirements is met, the Chairman shall not docket the request, and shall return the application to the applicant with a statement that no action is being taken due to a failure to meet the threshold requirements for docketing.

Paragraph (c) provides that the Board shall consider each application for

reconsideration that has been docketed under paragraph (b). This paragraph also provides that the final decision on reconsideration shall involve a different Board than the one that initially considered the application.

Paragraph (d) provides that the Board's final action on docketed application for reconsideration shall be the same as if they were original applications for correction.

Paragraph (e) provides that an applicant's request for reconsideration must be filed within two years after the issuance of a final decision, subject to other legal rules such as the Soldier's and Sailor's Civil Relief Act. The two-year statute of limitations parallels the time period allowed by Article 73 of the Uniform Code of Military Justice for petitioning for a new trial after the approval of a court-martial sentence on the grounds of newly discovered evidence or fraud on the court. If the Chairman docketed an applicant's request for reconsideration under paragraph (b), the two-year requirement may be waived if the Board finds that it would be in the interest of justice to consider the request despite its untimeliness.

Regulatory Process Matters

This is not a significant rule under Executive Order 12681 or the Department's Regulatory Policies and Procedures. The costs of a purely procedural change in the Board's rule would be negligible. The rule will not have a significant economic effect on a substantial number of small entities, as defined in the Regulatory Flexibility Act. There are no Federalism factors to warrant the preparation of a Federalism assessment.

List of Subjects in 33 CFR Part 52

Administrative practice and procedure, Archives and records, Military personnel, Military records.

Issued this 8th day of May 1996, at Washington, D.C.

Federico Peña,
Secretary of Transportation.

For the reasons set forth in the preamble, the Office of the Secretary of the U.S. Department of Transportation amends 33 CFR Part 52 as follows:

PART 52—[AMENDED]

1. The authority citation for Part 52 is revised to read as follows:

Authority: 10 U.S.C. 1552; 49 U.S.C. 108; Pub. L. 101-225, 103 Stat. 1908, 1914.

2. Section 52.67 is revised to read as follows:

§ 52.67 Reconsideration.

(a) Reconsideration of an application for correction of a military record shall occur if an applicant requests it and the request meets the requirements set forth in paragraph (a)(1) or (a)(2) of this section.

(1) An applicant presents evidence or information that was not previously considered by the Board that could result in a determination other than that originally made. Evidence or information may only be considered if it could not have been presented to the Board prior to its original determination if the applicant had exercised reasonable diligence; or

(2) An applicant presents evidence or information that the Board, or the Secretary as the case may be, committed legal or factual error in the original determination that could have resulted in a determination other than that originally made.

(b) The Chairman shall docket a request for reconsideration of a final decision if it meets the requirements of paragraph (a)(1) or (a)(2) of this section. If neither of these requirements is met, the Chairman shall not docket such request.

(c) The Board shall consider each application for reconsideration that has been docketed. None of the Board members who considered an applicant's original application for correction shall participate in the consideration of that applicant's application for reconsideration.

(d) Action by the Board on a docketed application for reconsideration is subject to § 52.64(b).

(e) An applicant's request for reconsideration must be filed within two years after the issuance of a final decision, except as otherwise required by law. If the Chairman docketed an applicant's request for reconsideration, the two-year requirement may be waived if the Board finds that it would be in the interest of justice to consider the request despite its untimeliness.

[FR Doc. 96-12030 Filed 5-13-96; 8:45 am]

BILLING CODE 4910-62-P

Coast Guard**33 CFR Part 117**

[CGD09-96-003]

RIN 2115-AE47

Drawbridge Operation Regulations; Saginaw River, MI

AGENCY: Coast Guard, DOT.

ACTION: Direct final rule.

SUMMARY: By this direct final rule, the Coast Guard is revising the regulations governing the operations of the CSX (formerly the Chessie System) railroad bridge at mile 18.0 over the Saginaw River in Saginaw, Michigan. The owners have made a request to the Coast Guard to maintain the bridge as a fixed structure with the stipulation and understanding that the bridge may be placed back into operation within six months upon notification of the Coast Guard.

DATES: This rule is effective on August 12, 1996, unless the Coast Guard receives written adverse comments or written notice of intent to submit adverse comments on or before July 15, 1996. If such comments or notice are received, the Coast Guard will withdraw this direct final rule, and a timely notice of withdrawal will be published in the Federal Register.

ADDRESSES: Comments may be mailed to Commander (obr), Ninth Coast Guard District, 1240 E. Ninth St., Cleveland, OH 44199-2060, or may be delivered to room 2083 at the same address between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (216) 522-3993.

The District Commander maintains the public docket for this rulemaking. Comments will become part of this docket and will be available for inspection or copying at the above address during the same time.

FOR FURTHER INFORMATION CONTACT: Mr. Scott M. Striffler, Project Manager, at (216) 522-3993.

SUPPLEMENTARY INFORMATION:**Request for Comments**

Any comments must identify the name and address of the person submitting the comment, specify the rulemaking docket (CGD09-96-003) and the specific section of this rule to which each comment applies, and give the reason for each specific comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

Regulatory Information

The Coast Guard is publishing a direct final rule, the procedures of which are outlined in 33 CFR 1.05-55, because no adverse comments are anticipated. If no adverse comments or any written notices of intent to submit adverse comment are received within the specified comment period, this rule will

become effective as stated in the **DATES** section. In that case, approximately 30 days prior to the effective date, the Coast Guard will publish a notice in the Federal Register stating that no adverse comment was received and confirming that this rule will become effective as scheduled. However, if the Coast Guard receives written adverse comment or written notice of intent to submit adverse comment, the Coast Guard will publish a notice in the final rule section of the Federal Register to announce withdrawal of all or part of this direct final rule. If adverse comments apply to only part of this rule, and it is possible to remove that part without defeating the purpose of this rule, the Coast Guard may adopt as final those parts of this rule on which no adverse comments were received. The part of this rule that was the subject of adverse comment will be withdrawn. If the Coast Guard decides to proceed with a rulemaking following receipt of adverse comments, a separate Notice of Proposed Rulemaking (NPRM) will be published and a new opportunity for comment provided.

A comment is considered "adverse" if the comment explains why this rule would be inappropriate, including a challenge to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change.

Background and Purpose

The placement of a movable bridge in a "fixed status" means that the bridge is essentially locked in the closed position and all the operating gear removed. This rule will allow the owners (CSX Railroad Corp.) of the CSX (formerly the Chessie System) railroad bridge, at mile 18.0 over the Saginaw River in Saginaw, Michigan, to maintain the bascule bridge in a "fixed status". The owners initiated this action due to the absence of any requests to open the bridge for commercial traffic since 1988. Furthermore, the bridge is unattended and subject to high maintenance costs from recurring vandalism. As part of the background for this rulemaking, the Coast Guard requested bridgetender logs for the previous five years, but CSX stated that it did not maintain records for this bridge during the period because no requests for openings were made. The Coast Guard asked for confirmation of the owner's claims from the local Coast Guard Station in Saginaw, Michigan. The Station verified that the bridge had not opened within the experience of the personnel assigned there. The Station also noted that they are not aware of any commercial traffic that has, or will have, a need to pass