

FDA is issuing this companion proposed rule to amend certain existing regulations to conform to amendments made by FDAMA to section 510(g) of the act. For a discussion of the specific provisions of the regulation, see the preamble to the direct final rule published elsewhere in this issue of the **Federal Register**.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impact of this companion proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121)), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulatory action is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, this proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The rule codifies applicable statutory requirements imposed by FDAMA. Because the companion proposed rule exempts certain distributors from registration and device listing, it may permit more small competitors to enter the marketplace. The agency certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule does not impose a mandate that results in an expenditure of \$100 million or more in either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the

Unfunded Mandates Reform Act of 1995 is not required.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

V. Submission of Comments

Interested persons may, on or before December 14, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. The comment period runs concurrently with the comment period for the direct final rule. Two copies of any comment are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered as comments regarding the direct final rule and this proposed rule. In the event the direct final rule is withdrawn, all comments received will be considered comments on the proposed rule.

List of Subjects in 21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 807 be amended as follows:

1. The part heading for part 807 is revised to read as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

2. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374.

3. Section 807.3 is amended by revising paragraphs (d)(2) and (g), and by adding paragraph (s) to read as follows:

§ 807.3 Definitions.

* * * * *

(d) * * *

(2) Initial importation of devices manufactured in foreign establishments; or

* * * * *

(g) Initial importer means any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes the final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.

* * * * *

(s) Wholesale distributor means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.

4. Section 807.20 is amended by revising paragraph (a)(4), by redesignating paragraph (d) as paragraph (c) and paragraph (c) as paragraph (d), respectively, and by adding paragraph (c)(3) to read as follows:

§ 807.20 Who must register and submit a device list.

(a) * * *

(4) Acts as an initial importer;

* * * * *

(c) * * *

(3) Acts as a wholesale distributor, as defined in § 807.3(s), and who does not manufacture, repackage, process, or relabel a device.

* * * * *

§ 807.22 [Amended]

5. Section 807.22 *How and where to register establishments and list devices* is amended in paragraph (c) by removing the words “distributor” and “distributors” each time they appear and by adding in their place the words “initial importer” and “initial importers”, respectively.

Dated: July 15, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–25797 Filed 9–28–98; 8:45 am]

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DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 581

[AR 15–185]

Army Board for Correction of Military Records

AGENCY: Assistant Secretary of the Army for Manpower and Reserve Affairs, DOD.

ACTION: Proposed rule.

SUMMARY: The Department of the Army proposes to amend its regulation on Army Board for Correction of Military Records to bring it in line with changes to Army Regulation 15-185, with the same title. This proposal updates the policies and procedures for consideration of applications, and corrections of the military records process. The section implements portions of Title 10, U.S. Code 1034, and Department of Defense (DOD) Directive 7050.6, Military Whistleblower Protection, that pertain to actions by the Army Board for Correction of Military Records. It also implements DoD Instruction 1336.6 Correction of Military Records and streamlines portions of the application process by transferring the information into a Department of the Army Pamphlet.

DATES: Comments must be received not later than October 29, 1998.

ADDRESSES: Comments may be sent to The Army Review Boards Agency, ATTN: SFMR-RBR, 1941 Jefferson Davis Highway, Arlington, VA 22202-4508.

FOR FURTHER INFORMATION CONTACT: Ms. Gale Thomas, Military Personnel Management Specialist, (703) 607-2044.

SUPPLEMENTARY INFORMATION: Section 581.3 contained in 32 CFR part 581 provides Department of the Army policy, criteria and administrative instructions regarding an applicant's request for the correction of a military record.

Executive Order 12866

This proposed rule is not a significant regulatory action pursuant to Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, the proposed rule will not have an annual effect on the economy of \$100 million or have a significant impact on a substantial number of small entities. The proposed rule only concerns the release of information that pertains to Federal records.

Paperwork Reduction Act

In compliance with The Paperwork Reduction Act, information collection is required on Department of Defense Form 149 titled "Application for Correction of Military Record". The form is necessary to identify specific types of information in support of the Army Board requirements. The form was approved previously by the Office

of Management Budget (OMB) and assigned OMB Control No. 0704-0003.

List of Subjects in 32 CFR Part 581

Administrative practice and procedure, Archives and Records, Military Personnel.

Accordingly, part 581 is proposed to be amended as follows:

1. The authority citation for 581 continues to read as follows:

Authority: 10 U. S. C. 1552, 1553, 1554, 3012; 38 U. S. C. 3103a.

2. Section 581.3 is proposed to be revised to read as follows:

§ 581.3 Army Board for Correction of Military Records.

(a) General.—(1) *Purpose.* This section prescribes the policies and procedures for correction of military records by the Secretary of the Army, acting through the Army Board for Correction of Military Records (ABCMR).

(2) *Statutory authority.* Title 10 U. S. C. Section 1552, Correction of Military Records: Claims Incident Thereto (10 U. S. C. 1552), is the statutory authority for this section.

(b) *Responsibilities.*—(1) *The Secretary of the Army.* The Secretary of the Army will oversee the operations of the ABCMR. The Secretary will take final action on applications as appropriate.

(2) *The ABCMR Director.* The ABCMR Director will manage the ABCMR's day-to-day operations.

(3) *The Chair.* The Chair of a given ABCMR panel will preside over the ABCMR panel, conduct a hearing, maintain order, ensure the applicant receives a full and fair opportunity to be heard and certify the written record of proceedings in pro forma and formal hearings as being true and correct.

(4) *The ABCMR members.* The ABCMR members will—

(i) Review all applications properly before them, to determine the existence of error or injustice.

(ii) If persuaded that probable material error or injustice exists, and sufficient evidence exist on the record, direct or recommend changes in military records to correct the error or injustice.

(iii) Recommend a hearing when appropriate in the interest of justice.

(iv) Deny applications where the alleged error or injustice is not adequately supported by the evidence, and a hearing is not deemed proper.

(v) Deny applications where the application is not timely filed, and it is not in the interest of justice to excuse the failure to timely file.

(5) *The Army records holding agency.* The Army records holding agency will—

(i) Take appropriate action on routine issues that may be administratively corrected under authority inherent in the custodian of the records and do not require ABCMR action.

(ii) Furnish all requested Army military records to the ABCMR.

(iii) Request additional information from the applicant, if needed, to assist the ABCMR in conducting a full and fair review of the matter.

(iv) Take corrective action directed by the ABCMR or the Secretary of the Army.

(v) Inform the Defense Finance and Accounting Service (DFAS), when appropriate, the applicant, his or her counsel, if any, and interested Members of Congress, if any, after a correction is complete.

(vi) Return original records of the soldier or former soldier obtained from the Department of Veterans Affairs (VA).

(6) *The Army staff agencies and commands.* The Army staff agencies and commands will—

(i) Furnish advisory opinions on matters within their areas of expertise upon request of the ABCMR, within a timely manner.

(ii) Obtain additional information or documentation as needed before providing the opinions to the ABCMR.

(iii) Provide records, investigations, information, and documentation upon request of the ABCMR.

(iv) Provide additional assistance upon request of the ABCMR.

(v) Take corrective action directed by the ABCMR or the Secretary of the Army.

(7) *DFAS.* The ABCMR staff will request that DFAS—

(i) Furnish advisory opinions on matters within its area of expertise upon request.

(ii) Obtain additional information or documentation as needed before providing the opinions.

(iii) Provide financial records upon request.

(iv) Settle claims on behalf of the Army based on ABCMR final actions.

(v) Report quarterly on the monies expended as a result of ABCMR action, and the names of the payees, to the ABCMR Director.

(c) *ABCMR establishment and functions.*—(1) *ABCMR Establishment.* The ABCMR operates pursuant to law (10 U. S. C. 1552) within the Office of the Secretary of the Army. The ABCMR consists of civilians regularly employed in the executive part of the Department of the Army (DA), who are appointed by the Secretary of the Army, and who

serve on the ABCMR as an additional duty. Three members constitute a quorum.

(2) *ABCMR Functions.* (i) The ABCMR considers individual applications properly brought before it. In appropriate cases, it directs or recommends correction of military records to remove an error or injustice.

(ii) When an applicant has suffered reprisal under the Military Whistleblower Protection Act (10 U. S. C. 1034 and Department of Defense Directive (DODD) 7050.6), the ABCMR may recommend to the Secretary of the Army that disciplinary or administrative action be taken against any Army official who committed an act of reprisal against the applicant.

(iii) The ABCMR will decide cases on the evidence of record. It is not an investigative body. The ABCMR may, in its discretion, hold a hearing (sometimes referred to as an evidentiary hearing or an administrative hearing in 10 U. S. C. 1034 and DODD 7050.6), or call for additional evidence or opinions.

(d) *Application procedures.*—(1) *Who may apply.* The ABCMR's jurisdiction under 10 U. S. C. 1552 extends to any military record of the DA. It is the nature of the record, and/or the status of the applicant, that defines the ABCMR's jurisdiction.

(i) Usually applicants are soldiers or former soldiers of the active Army, the U.S. Army Reserve (USAR), and in certain cases, the Army National Guard (ARNG), and other military and civilian individuals affected by an Army military record. Requests are personal to the applicant and relate to military records. Requests are submitted on Department of Defense (DD) Form 149, Application for Correction of Military Record. Soldiers in an active or reserve status need not submit applications via their chain of command.

(ii) An applicant with a proper interest may request correction of another person's military records when that person is incapable of acting on his or her own behalf, is missing, or is deceased. Depending on the circumstances, a child, spouse, parent or other close relative, an heir, or legal representative (such as a guardian or executor) of the soldier or former soldier may be able to show a proper interest. Applicants must send proof of proper interest with the application when requesting correction of another person's military records.

(2) *Time limits.* Applicants must file an application within 3 years after the alleged error or injustice was discovered or should have been discovered. The ABCMR may deny an untimely

application. The ABCMR may excuse untimely filing in the interest of justice.

(3) *Administrative remedies.* The ABCMR will not consider an application until the applicant has exhausted all administrative remedies to correct the alleged error or injustice.

(4) *Stay of other proceedings.* Applying to the ABCMR does not stay other proceedings.

(5) *Counsel.* (i) Applicants may be represented by counsel, at their own expense.

(ii) See DODD 7050.6 for provisions for counsel in cases processed under 10 U. S. C. 1034.

(e) *Application processing.* (1) Actions by the ABCMR Director and staff. The ABCMR staff will review each application to determine if it meets the criteria for consideration by the ABCMR. The application may be returned without action if:

(i) The applicant fails to complete and sign the application.

(ii) The applicant has not exhausted all other administrative remedies.

(iii) The ABCMR does not have jurisdiction to grant the requested relief.

(iv) No new evidence was submitted with a request for reconsideration.

(2) *Burden of proof.* The ABCMR begins its consideration of each case with the presumption of administrative regularity. The applicant has the burden of proving an error or injustice by a preponderance of the evidence.

(3) *ABCMR consideration.* (i) A panel consisting of at least three ABCMR members shall consider each application properly brought before it. One panel member serves as its chair.

(ii) The panel may consider the case on the merits in executive session or authorize a hearing.

(iii) Each application will be reviewed to determine:

(A) Whether the preponderance of the evidence shows that an error or injustice exists.

(1) If so, what relief is appropriate.

(2) If not, deny relief.

(B) Whether to authorize a hearing.

(C) If the application is filed outside the statute of limitations, whether to deny based on untimeliness or to waive the statute in the interest of justice.

(f) *ABCMR hearings.* Applicants do not have a right to a hearing before the ABCMR. The Director or the ABCMR may grant a formal hearing whenever justice requires.

(g) *Disposition of applications.* (1) *ABCMR decisions.* The panel's majority vote constitutes the action of the ABCMR. The ABCMR's findings, recommendations, and, in the case of a denial, the rationale will be in writing.

(2) *ABCMR final action.* (i) The ABCMR acts for the Secretary of the Army and its decision is final when it: (A) Denies any application (except under 10 U.S.C. 1034).

(B) Grants any application in whole or in part without a hearing when:

(1) The relief is as recommended by the proper staff agency in an advisory opinion; and

(2) Is unanimously agreed to by the ABCMR panel; and

(3) Does not involve an appointment or promotion requiring confirmation by the Senate.

(ii) The ABCMR will forward the decisional document to the Secretary of the Army for final decision in any case where:

(A) A hearing was held.

(B) The facts involve reprisals under the Military Whistleblower Protection Act confirmed by the Department of Defense Inspector General (DODIG) under 10 U.S.C. 1034 and DODD 7050.6.

(C) The ABCMR recommends relief, but is not authorized to act for the Secretary of the Army on the application.

(3) *Decision of the Secretary of the Army.* (i) The Secretary of the Army may direct such action as he or she deems proper on each case. Cases returned to the Board for further consideration will be accompanied by a brief statement of the reasons for such action. If the Secretary does not accept the ABCMR's recommendation, or adopts a minority position, or fashions an action that he or she deems proper and supported by the record, that decision will be in writing and will include a brief statement of the grounds for denial or revision.

(ii) The Secretary of the Army will issue decisions on cases covered by the Military Whistleblower Protection Act (10 U.S.C. 1034 and DODD 7050.6). In cases where the DODIG concluded that there was reprisal, these decisions will be made within 180 days after receipt of the application and the investigative report by the DODIG, the Department of the Army Inspector General (DAIG), or other Inspector General (IG) offices. Unless the full relief requested is granted, these applicants will be informed of their right to request review of the decision by the Secretary of Defense.

(4) *Reconsideration of applications.* An applicant may ask the ABCMR to reconsider its decision under the following circumstances:

(i) If the ABCMR receives the request within 1 year of the ABCMR's action, and the ABCMR has not previously reconsidered the matter, the ABCMR staff will review the request to

determine if it includes evidence (including, but not limited to, any facts or arguments as to why relief should be granted) that was not in the record at the time of the ABCMR's prior consideration. If new evidence has been submitted, the request will be submitted to the ABCMR for its determination of whether new evidence exists sufficient to show probable material error or injustice. If no new evidence is found, the ABCMR staff will return the application to the applicant without action.

(ii) If the ABCMR receives the request more than 1 year after the ABCMR's action, or after the ABCMR has already considered one request for reconsideration, the ABCMR staff will review the request to determine if substantial relevant evidence is submitted showing fraud, mistake of law, mathematical miscalculation, manifest error, or the existence of substantial, relevant new evidence discovered contemporaneously or within a short time after the ABCMR's original consideration. If the ABCMR staff finds such evidence, it will be submitted to the ABCMR for its determination of whether a material error or injustice exists, and if so, the proper remedy. If the ABCMR staff does not find such evidence, the application will be returned to the applicant without action.

(h) *Claims/Expenses.*—(1) *Authority.* (i) The Army, by law, may pay claims for amounts due to applicants as a result of correction of military records.

(ii) The Army may not pay any claim previously compensated by Congress through enactment of a private law.

(iii) The Army may not pay for any benefit to which the applicant might later become entitled under the laws and regulations managed by the VA.

(2) *Settlement of claims.* (i) The ABCMR will furnish DFAS copies of decisions potentially affecting monetary entitlement or benefits. DFAS will treat such decisions as claims for payment by or on behalf of the applicant.

(ii) DFAS will settle claims on the basis of the corrected military record. DFAS will compute the amount due, if any. DFAS may require applicants to furnish additional information to establish their status as proper parties to the claim and/or to aid in deciding amounts due. Earnings received from civilian employment during any period for which active duty pay and allowances are payable will be deducted. The applicant's acceptance of a settlement fully satisfies the claim concerned.

(3) *Payment of expenses.* The Army may not pay attorney's fees or other

expenses incurred by or on behalf of an applicant in connection with an application for correction of military records under 10 U.S.C. 1034 or 1552.

(i) *Miscellaneous provisions.*—(1) *Special standards.* (i) Pursuant to the November 27, 1979 order of the United States District Court for the District of Columbia in *Giles v. Secretary of the Army* (Civil Action No. 77-0904), a former Army service member is entitled to an honorable discharge if a less than honorable discharge was issued to the service member, on or before November 27, 1979, in an administrative proceeding in which the Army introduced evidence developed by or as a direct or indirect result of compelled urinalysis testing administered for the purpose of identifying drug abusers (either for the purposes of entry into a treatment program or to monitor progress through rehabilitation or follow-up).

(ii) Applicants who believe that they fall within the scope of paragraph (i) (1)(i) of this section should place the word CATEGORY "G" in block 11, (DD Form 149) Application for Correction of Military or Naval Record. Such applications should be viewed expeditiously by a designated official who will either send the individual an honorable discharge certificate if the individual falls within the scope of paragraph (i) (1)(i) of this section, or forward the application to the Discharge Review Board if the individual does not fall within the scope of paragraph (i) (1)(i) of this section. The action of the designated official shall not constitute an action or decision by the Board for Correction of Military Records.

(2) *Public access to decisions.* (i) After deletion of personal information, a redacted copy of each decision will be indexed by subject and made available for review and copying at a public reading room at Crystal Mall 4, 1941 Jefferson Davis Highway, Arlington, Virginia. The index will be in a usable and concise form so as to indicate the topic considered and the reasons for the decision. Under the Freedom of Information Act, 5 U.S.C. 552, records created on or after November 1, 1996 shall be available by electronic means.

(ii) Under the Freedom of Information Act, 5 U.S.C. 552, and the Privacy Act of 1974, 5 U.S.C. 552(a), the ABCMR will not furnish to third parties information submitted with or about an application unless specific written authorization is received from the

applicant, or as otherwise authorized by law.

Loren G. Harrell,

Director, Army Board for Correction of Military Records.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 55

[USCG 1998-3821]

RIN 2115-AF48

Coast Guard Child Development Services Programs

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish child development services for eligible children of the Department of Transportation military and civilian personnel and eligible children of armed forces members and federal civilian employees. This proposed rule also establishes the basis for a "total family income" sliding fee schedule to make child care more affordable for lower-income families in center-based programs. This proposed rule also provides a mechanism to reduce fees for users of family child care providers through the use of appropriated funds.

DATES: Comments must reach the Docket Management Facility on or before October 29, 1998.

ADDRESSES: You may mail comments to the Docket Management Facility, (USCG 1998-3821), U.S. Department of Transportation, room PL-401, 400 Seventh Street SW., Washington, DC 20590-0001, or deliver them to room PL-401, located on the Plaza Level of the Nassif Building at the same address between 10 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

The Docket Management Facility maintains the public docket for this rulemaking. Comments will become part of this docket and will be available for inspection or copying at room PL-401, located on the Plaza Level of the Nassif Building at the same address between 10 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also access this docket on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT:

For questions about the docket, contact Ms. Paulette Twine, Chief, Documentary