introduced into commercial distribution under the same 510(k) or premarket approval application, may be considered in grouping products into device families.As part of implementation of the final regulation, FDA will provide further information, guidance and examples.

4. Comments objected to the requirement on the annual certification form for manufacturers (FDA Form 3381) that the firm certify not only the number of reports submitted during the 12-month period for which the certification is submitted, but also that this number constitutes all the reportable events for which the firm is responsible during that period.

FDA responded to similar comments in the preamble to the final rule (60 FR 63578 at 63591). For the reasons stated therein, FDA still believes that it is necessary and within FDA's statutory authority to require that manufacturers certify that they have submitted all reportable events to FDA. FDA believes that certification is an important means of increasing the effectiveness of the Medical Device Reporting (MDR) system. FDA, however, realizes that there may be situations, hopefully rare, when a manufacturer, for example, did not ''become aware,'' as defined in 803.1(c) (21 CFR 803.1(c)), of information reasonably suggesting a reportable event has occurred, and therefore could not have submitted a report, or there may be an occasional instance of miscounting the number of reports. FDA, therefore, has determined that it is appropriate for manufacturers to state that they are certifying the statements on FDA Form 3381 to the best of their knowledge. FDA has revised the form accordingly. It now states:

I certify that, to the best of my knowledge, the firms listed in item 3. above either submitted the MDR indicated above during the stated reporting period and that this number represents the submissions for all appropriately reportable MDR events or that the firm listed above did not receive any MDR reportable events during this time period. I also certify that, to the best of my knowledge, the statements and information presented in this submission are truthful and accurate.

5. Comments objected to the requirement that annual updates to baseline reports be submitted on the anniversary date of the initial baseline report. The comments noted that, for companies who submit baseline reports for numerous devices, they would have to keep track of many different submission dates for update baseline reports. The comments suggested that manufacturers be allowed to submit all baseline updates on a single date, e.g., the date on which annual certification is required.

FDA agrees with the comments and believes that it is an acceptable interpretation of the regulation to allow an annual update on the date on which the annual certification is due.

Section 803.55(a) requires that a manufacturer shall submit its first baseline report ''for a device when the device model is first reported under § 803.50'' (i.e., an individual adverse event report). Section 803.55(b) requires that each baseline report shall be updated annually, on the anniversary month of the initial submission. The time a manufacturer is required to submit the update of their baseline report under § 803.55(b), is therefore contingent upon the time a manufacturer is considered to have ''first reported'' an adverse event for a particular device model.

FDA believes that a manufacturer could interpret § 803.55(a) to mean that the first baseline report update could be submitted on the date a firm is required to submit its next certification. Accordingly, the firm could thereafter submit its annual baseline update report on the date of the firm's next annual certification. For example, if a manufacturer submits its first adverse event baseline report for a device on March 1, 1996, it could submit its first baseline report on the date of its next certification report, November 1, 1996. Thereafter, it would submit its update baseline report on November 1, 1997.

FDA intends to make a guidance document on the final rule available during April 1996, and will announce it's availability in the Federal Register. FDA also intends to hold a nationwide teleconference by satellite on May 7, 1996, during which FDA officials will speak on the final rule and be available to answer questions. When more details are available, FDA will publicize these initiatives through the Facts-on-Demand system administered by FDA's Division of Small Manufacturers Assistance, Center for Devices and Radiological Health, and the electronic docket. To access this information through Facts-on-Demand dial 1–800–899–0381 (outside MD) or 1–301–827–0111 (inside MD) and enter document number 799.

Dated: March 30, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8970 Filed 4–5–96; 3:26 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 811

[Docket No. FR–3985–C–02]

RIN 2502–AG64

Office of the Assistant Secretary for Housing-Federal Housing Commissioner: Regulatory Reinvention; Tax Exemption of Obligations of Public Housing Agencies and Related Amendments; Final Rule; Correction

AGENCY: Office of the Assistant Secretary for Housing-Federal Housing Commissioner, HUD.

ACTION: Final rule; correction.

SUMMARY: On April 1, 1996 (61 FR 14456), HUD published a final rule streamlining its regulations governing the tax exemption of obligations of public housing agencies. The preamble to the April 1, 1996 final rule stated that HUD was removing subpart B of 24 CFR part 811. However, the rule's regulatory text did not contain an amendatory instruction removing this subpart. The purpose of this document is to correct the April 1, 1996 final rule by removing 24 CFR part 811, subpart B.

FOR FURTHER INFORMATION CONTACT: James Mitchell, Director, Financial Services Division, Department of Housing and Urban Development, 470 L'Enfant Plaza East, room 3120, Washington, DC 20024, telephone number (202) 708–7450, ext. 125 (this is not a toll-free number). For hearing- and speech-impaired persons, this number may be accessed via TTY by calling the Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: On March 4, 1995, President Clinton issued a memorandum to all Federal departments and agencies regarding regulatory reinvention. In response to this memorandum, HUD conducted a page-by-page review of its regulations to determine which could be eliminated, consolidated, or otherwise improved. As part of this review, HUD examined its regulations at 24 CFR part 811, which govern the tax exemption of obligations of public housing agencies. HUD determined that 24 CFR part 811 could be improved and streamlined by eliminating unnecessary provisions.

On April 1, 1996 (61 FR 14456), HUD published a final rule which streamlined part 811 by eliminating provisions that were redundant of statutes or otherwise unnecessary. The program described in subpart B of part 811, concerning the purchase of GNMA

guaranteed mortgage-backed securities with tax exempt obligations, had never been implemented by HUD. Accordingly, the preamble to the April 1, 1996 final rule stated that HUD was removing this subpart. However, the regulatory text of the final rule did not contain an amendatory instruction removing 24 CFR part 811, subpart B. This document makes the necessary correction.

Accordingly, FR-Doc. 7949, a final rule published in the Federal Register on April 1, 1996 (61 FR 14456) is corrected by adding an amendatory instruction number 13 to the end of the document on page 14463 to remove subpart B of 24 CFR part 811, to read as follows:

Subpart B—[Removed]

13. Subpart B, consisting of §§ 811.201 through 811.211, is removed.

Dated: April 5, 1996.

Camille E. Acevedo,

Assistant General Counsel for Regulations.

[FR Doc. 96–8975 Filed 4–10–96; 8:45 am]

BILLING CODE 4210–27–P

DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 865

RIN 0701–AA43

Personnel Review Boards

AGENCY: Department of the Air Force, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Air Force has revised Part 865, Subpart A of Subchapter G, Title 32 of the Code of Federal Regulations, which provides for making application, and the consideration of applications, for the correction of military records by the Secretary of the Air Force acting through the Air Force Board for Correction of Military Records.

EFFECTIVE DATE: March 1, 1996.

FOR FURTHER INFORMATION CONTACT: Mr. John J. D'Orazio, Chief Examiner, (301) 981–3502.

SUPPLEMENTARY INFORMATION: On July 26, 1994, the Department of the Air Force published (at 59 FR 37953) a proposed rule changing the procedures for making applications, and consideration of applications, for the correction of military records by the Secretary of the Air Force acting through the Air Force Board for Correction of Military Records. The following summarizes the major comments received and action taken:

Two commentors stated that the rule should be amended to include specific references concerning other administrative remedies which must be exhausted prior to the submission of an application to the Board (§ 865.4(l)(3)). Information related to this rule is contained in Air Force Pamphlet (AFP) 36–2607, Applicant's Guide to the Air Force Board for Correction of Military Records (AFBCMR), dated 3 November 1994. In addition, it is normally expected that an active member would be made aware of any available administrative remedies by seeking advice from personnel at their local Military Personnel Flight (MPF). Furthermore, exhausting administrative remedies also refers to cases where an application for correction of records is submitted by members or former members and authorities at the MPF or the Air Force Personnel Center, Randolph AFB, Texas, determine that an error exists and that administrative relief may be effected by the Air Force office of primary responsibility without referring the appeal to the Board. The only other organization to which a former member must apply prior to submitting an application to the AFBCMR is the Air Force Discharge Review Board (AFDRB), which operates under its own statute (10 U.S.C. 1553) and Air Force Instruction (AFI) 36–2023, dated 14 October 1994. In view of the above, and, since the cited information is already available through other sources and would be made known to applicants who are inquiring about the Board process, amendment of the rule to include this information is deemed unnecessary.

Two commentors suggested that the rule should be amended to state that time spent exhausting administrative remedies tolls the three-year time limit (§ 865.3(f)). The Board takes the position that, for practical reasons, efforts to seek other administrative remedies should not toll the three-year statute of limitations found at 10 U.S.C. 1552(b). This rule works no hardship on potential applicants since the Board may waive the failure to file within the three-year period if it determines it is in the interest of justice to do so. Whether to waive an untimely filing is a discretionary judgment to be made by the Board.

One commentor complained that the page limitation on briefs and rebuttals was too severe, was unrealistic, and did not define ''brief'' (§ 865.3 (i) and (j)). The Board considers the term ''brief'' to be self-explanatory. The rule already states that the limitation does not apply to evidence submitted in support of the appeal. The Board does not believe that the page limitations on briefs in support of an application and in rebuttal to the Air Staff evaluations are too severe. This rule was established to ensure that applicants and their counsels briefly and succinctly state their cases; prolixity hinders, rather than helps, the Board. In recognition that there exist cases of unusual complexity, the rule allows for a waiver of the page limitations by the Executive Director of the Board. Since the page limitation requirement was established in 1985, the authority to approve requests for waivers of this requirement has been liberally exercised to ensure adequate briefing of issues the Board considers important.

Two commentors stated that the rule should be changed (at § 865.8c) to provide for the payment of attorney's fees, with interest, asserting that such payments are authorized by 5 U.S.C. 5596(b). 5 U.S.C. 5596(b) applies to employees as defined in 5 U.S.C. 2105. The cited provision of law does not apply to members of the Armed Forces.

One commentor recommended that the rule be amended to place limitations on the writers of advisory opinions with respect to the number of pages, type of spacing, and ''unprofessional'' comments (§ 865.8(a)(2)). Air Staff advisories rarely exceed more than two or three pages except in cases where the issues are extremely complicated. Furthermore, while the applicant has two opportunities to state his or her case (in the initial submission and rebuttal), ordinarily, the staff must state their position all at once. What constitutes ''Unprofessional comments'' is in the eye of the beholder. The Board requires that the Air Staff provide unfettered opinions. If the Air Staff provides information not relevant to the case, the Board can and does elect not to rely on that information in making its final determination, in the same way it does when similar information is provided by an applicant or counsel.

Two commentors suggested that the rule be amended to include (at § 865.9) advice concerning appeals to Federal courts. The AFBCMR was established to correct military records. A discussion of Post-Board avenues of relief is not required by law nor would it be appropriate in a rule pertaining to nonadversarial proceedings for the purpose of securing administrative relief.

One commentor recommended that the rule be changed to include a statement that, during its consideration of the case in executive session, the Board gave genuine consideration to