caninum and *Uncinaria stenocephala*. The supplement is approved as of February 15, 1996, and the regulations are amended in § 520.1196 (21 CFR 520.1196) by revising the limitation in paragraph (c)(1)(iii) as above to reflect the correct limitation as is stated in the approved product labeling. The basis of approval is discussed in the freedom of information summary.

In addition, the heading of § 520.1196 is revised from ''pyrantel (as pamoate salt)'' to ''pyrantel pamoate'' in order to conform with titles of other sections.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this supplemental NADA qualifies for a 3-year marketing exclusivity period beginning February 15, 1996, because new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval were conducted or sponsored by the applicant. The exclusivity period applies only to use in animals weighing less than 5 pounds.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.1196 is amended by revising the section heading and in paragraph (c)(1)(iii) by revising the second sentence to read as follows:

§ 520.1196 Ivermectin and pyrantel pamoate chewable tablet.

* * * * *

(c) * * *

(1) * * *

(iii) * * * Recommended for dogs 6 weeks of age and older. * * *

* * * * *

Dated: March 28, 1996.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 96–8362 Filed 4–4–96; 8:45 am]

BILLING CODE 4160–01–F

---

21 CFR Part 814

[Docket No. 93N–0047]

RIN 0910–AA09

Medical Devices; Temporary Suspension of Approval of a Premarket Approval Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing procedures to order the temporary suspension of approval of a premarket approval application (PMA) for a medical device. This action is being taken under a new authority granted to the agency by the Safe Medical Devices Act of 1990 (the SMDA). Under this new authority, if, after providing an opportunity for an informal hearing, FDA determines there is a reasonable probability that continued distribution of a device would cause serious, adverse health consequences or death, the agency shall, by order, temporarily suspend approval of a PMA, and proceed expeditiously, but within 60 days, to permanently withdraw approval of the PMA. The final rule also clarifies that these procedures apply to an original PMA, as well as any PMA supplement(s), for a medical device.

EFFECTIVE DATE: May 6, 1996.

FOR FURTHER INFORMATION CONTACT: Lisa A. Rooney, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765, ext. 164.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of October 12, 1993 (58 FR 52729), FDA published a proposed rule to establish procedures to order the temporary suspension of approval of a PMA for a medical device. Interested persons were given until December 13, 1993, to comment on the proposed rule. The agency received four comments, one from a trade association, and three from manufacturers.

II. Summary of the Final Rule

Section 9 of the SMDA (Pub. L. 101–629) amended section 515(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(e)) by adding section 515(e)(3) of the act which provides the agency with the authority to temporarily suspend approval of a PMA. This authority applies to the original PMA, as well as any PMA supplement(s), for a medical device. Section 515(e)(3) of the act and new § 814.47, the implementing regulation, provide the agency with a prompt method of removing dangerous devices from the market pending resolution of permanent PMA or PMA supplement withdrawal proceedings.

Under § 814.47(a), FDA will issue an order temporarily suspending approval of a PMA or a PMA supplement when FDA determines that there is a reasonable probability that continued distribution of the device would cause serious, adverse health consequences or death.

Pursuant to § 814.47(b), when FDA makes the requisite determination, FDA shall provide an opportunity for an informal hearing to determine whether to issue an order temporarily suspending approval of a PMA or a PMA supplement. Such an informal hearing is to be initiated and conducted by FDA pursuant to part 16 (21 CFR part 16). Generally, under § 814.47(b)(2), the person provided with notice of an opportunity for an informal hearing will have not less than 3 working days after receipt of the notice to request a hearing. Moreover, the informal hearing ordinarily will not be held less than 2 working days after receipt of the request for the hearing, in order to provide time for preparation. However, in those rare circumstances when FDA believes that immediate action to remove a dangerous device from the market is necessary to protect the public health, the agency may waive, suspend, or modify the above-referenced timeframes in accordance with § 10.19 (21 CFR 10.19) and § 16.60(h).

Under § 814.47(b)(3), a PMA holder's or a PMA supplement holder's failure to request a hearing within the timeframe specified by FDA in the notice of opportunity for a hearing, which is generally not less than 3 working days, is deemed a waiver of the hearing.

Pursuant to § 814.47(c), if the PMA or PMA supplement holder does not request a hearing or after an informal hearing, FDA shall, by order, temporarily suspend approval of a PMA or PMA supplement if the agency determines there is a reasonable probability that continued distribution of the device would cause serious, adverse health consequences or death. In accordance with § 814.47(d), FDA shall proceed expeditiously, but within 60 days, to permanently withdraw approval of the PMA or PMA supplement.

III. Clarification of the Proposed Rule

This final rule clarifies that the procedures for ordering the temporary suspension of approval of a PMA apply to both the original PMA and any PMA supplement(s) for a medical device. A PMA supplement is a supplemental application for approval of a change affecting the safety or effectiveness of a device for which there is an approved PMA (see §§ 814.3(g) and 814.39). As discussed in the preamble to part 814 (21 CFR part 814) (51 FR 26342 at 26354, July 22, 1986), when an applicant submits a PMA supplement for a change in an approved device, the applicant has, in effect, submitted a new PMA for the ''new'' (changed) device. For this reason, FDA has concluded that the authority provided by section 515(e)(3) of the act applies to both PMA's and PMA supplement(s).

IV. Changes from the Proposed Rule

Although the agency maintained the basic framework of the proposed rule, FDA modified the proposed rule in order to be consistent and compatible with the medical device recall authority and to address concerns raised in the comments. Several comments raised due process concerns that resulted in FDA clarifying proposed § 814.47(b) and modifying proposed § 814.47(d).

FDA clarified that the hearing provided for in § 814.47(b) will be conducted, whenever possible, in accordance with the procedures set out in part 16. Thus, under § 814.47(b)(2), the person offered an opportunity for an informal hearing ordinarily will have not less than 3 working days after receipt of the notice to request a hearing. Moreover, the informal hearing ordinarily will not be held less than 2 working days after receipt of the request for the hearing. However, in extraordinary cases, if FDA believes that immediate action to remove a dangerous device from the market is necessary to protect the public health, the agency may waive, suspend, or modify the above-referenced timeframes in accordance with § 10.19 and 16.60(h).

Furthermore, FDA amended § 814.47(d) to specify a timeframe within which FDA must initiate permanent withdrawal of PMA or PMA supplement approval after issuing an order temporarily suspending PMA or PMA supplement approval. FDA concluded that following issuance of an order temporarily suspending approval of a PMA or a PMA supplement, the agency will proceed expeditiously, but within 60 days, to permanently withdraw approval of the PMA or the PMA supplement.

V. Relationship Between Temporary Suspension of Approval of a PMA or PMA Supplement and Medical Device Recall Authority

The SMDA provided FDA with, among other things, the authority to issue orders to temporarily suspend the approval of a PMA or a PMA supplement and to recall medical devices.

Section 8 of the SMDA amended section 518 of the act (21 U.S.C. 360h) by adding a new subsection (e) entitled ''Recall Authority.'' Section 518(e)(1) of the act provides that, if FDA finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, FDA shall issue an order requiring the appropriate person to immediately cease distribution of the device, immediately notify health professionals and device user facilities of the order, and instruct such professionals and facilities to cease use of the device. Section 518(e)(2) of the act states that, after providing an opportunity for an informal hearing, FDA may amend the cease distribution and notification order to require a recall of the device. FDA's medical device recall authority may be invoked for any class of device.

This recall authority may be invoked for targeted purposes, for example, when FDA wants an individual to temporarily cease distribution and/or recall certain lots, batches, or models of class I, class II, or class III devices which are located either in-house or on the market until such devices are brought into compliance; or, the recall authority may be used more broadly to cease distribution and/or recall all models, batches, or lots of a manufacturer's device. On the other hand, the agency's authority to temporarily suspend approval of a PMA or a PMA supplement is invoked only in the latter circumstance, when FDA wants a manufacturer to cease marketing all models, batches, or lots of a particular class III device which was approved under the subject PMA or PMA supplement, pending permanent withdrawal of the device's PMA or PMA supplement approval. Thus, there may be circumstances in which FDA could invoke both authorities.

The threshold criteria for invoking the medical device recall authority and the authority to temporarily suspend approval of a PMA or PMA supplement are identical. Under both authorities, FDA will issue orders only when FDA determines there is a reasonable probability that continued distribution of a device would cause serious, adverse health consequences or death. Furthermore, under both authorities, FDA must provide the person subject to the order and the holder of the approved PMA or PMA supplement for the device with an opportunity for an informal hearing. In both situations, the informal hearing is to be conducted by FDA pursuant to part 16.

If FDA determines that there is a reasonable probability that continued distribution of a currently marketed class III medical device would cause serious, adverse health consequences or death, the agency may invoke its medical device recall authority as well as its authority to temporarily suspend approval of the PMA or PMA supplement for the device. If both authorities are invoked, the medical device recall informal hearing will be combined with the temporary suspension of approval of a PMA or PMA supplement informal hearing. This combined informal hearing will occur after FDA makes the requisite finding, issues a cease distribution and notification order, and issues a letter of intent to temporarily suspend approval of a PMA or PMA supplement. This combined informal hearing does not eliminate the PMA or PMA supplement holder's opportunity for an informal hearing prior to FDA permanently withdrawing approval of a PMA or PMA supplement (see section 515(e)(1) of the act).

VI. Summary and Analysis of Comments and FDA's Response

1. One comment noted that the proposed rule, which states that ''FDA may initiate and conduct a regulatory hearing to determine whether to issue an order temporarily suspending approval of the PMA'' (§ 814.47(b)(1)), implies that FDA can use its own discretion in determining whether or not to hold a hearing prior to temporarily suspending PMA approval and is contrary to section 515(e)(1) and (e)(3) of the act and to the preamble of the proposed rule itself (see 58 FR

52729). Thus, it was urged that the final rule unequivocally state that FDA will provide the manufacturer with an opportunity for an informal hearing prior to temporarily suspending PMA approval.

FDA agrees with this comment. Under final § 814.47(b), FDA must give the PMA or PMA supplement holder notice and an opportunity for a regulatory hearing under part 16 prior to temporarily suspending PMA or PMA supplement approval. However, whether or not a regulatory hearing is actually conducted depends on the decision of the PMA or PMA supplement holder. If the PMA or PMA supplement holder does not request a regulatory hearing within the timeframe specified by FDA in the notice of opportunity for a hearing, then FDA may temporarily suspend approval of the PMA or PMA supplement without a hearing. On the other hand, if the PMA or PMA supplement holder requests the regulatory hearing within the timeframe specified by FDA in the notice of opportunity for a hearing, then FDA must conduct the hearing before temporarily suspending approval of the holder's PMA or PMA supplement.

2. Under § 814.47(b)(2), if FDA believes that immediate action to remove a dangerous device from the market is necessary to protect the public health, FDA may, pursuant to § 16.60(h), waive or modify any part 16 procedure in accordance with § 10.19. A comment noted that in this situation FDA can waive § 16.24(e), which states that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing. This comment recommended that, at the very least, § 16.60(h) should not apply to § 16.24(e). Another comment urged that the agency should not be allowed, under § 16.60(h), to waive the notice requirements of § 16.24(e), which states that a hearing may not be required to be held at a time less than 2 working days after receipt of the request for a hearing and § 16.22(b), which gives a person at least 3 days after receiving notice of an opportunity for a hearing to request one. The comment urged that waiver of these sections would violate a PMA holder's due process rights. Additionally, it was contended that §§ 16.22(b) and 16.24(e) cannot be waived because §§ 10.19 and 16.60(h) do not permit FDA to waive notice requirements. The comment requested that FDA insert language granting an informal hearing as defined in section 201(x) of the act (21 U.S.C. 321(x)) and specifying that notice of at least 10 calendar days is required prior to the issuance of an order temporarily suspending approval of a PMA. This same comment noted that, under § 10.19, waiver of prehearing requirements is only allowed ''if no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with the law.'' According to this comment, waiver of §§ 16.22(b) and 16.24(e) would violate section 515(e)(3) of the act, which requires the opportunity for an informal hearing.

FDA agrees that the hearing provided for in § 814.47(b)(2) should be conducted, whenever possible, within the timeframes set out in part 16. Thus, in accordance with § 16.22(b) of this chapter, under § 814.47(b)(2), the person offered an opportunity for an informal hearing ordinarily will have not less than 3 working days after receipt of the notice to request a hearing. Furthermore, pursuant to § 16.24(e), the informal hearing ordinarily will not be held less than 2 working days after receipt of the request for the hearing. However, under § 16.60(h), the Commissioner or the presiding officer has the power to waive any part 16 provision. According to § 10.19, part 16 provisions can only be suspended, modified, or waived if no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with the law. FDA can waive, modify, or suspend the timeframes associated with the regulatory hearings relating to suspension of PMA or PMA supplement approvals as long as the PMA or PMA supplement holder is given notice and an opportunity for an informal hearing as required by section 515(e)(3) of the act. In extraordinary cases, FDA could give the PMA holder notice, conduct a hearing, and render a decision on the same day. This would be consistent with Congress' intent that, for temporary suspension action, the informal hearing, when necessary, should be analogous to a temporary restraining order (TRO) hearing that could result in notice, a hearing, and a judicial decision in a single day if immediate action to remove a dangerous device from the market is absolutely necessary to protect the public health. (See H. Rept. 808, 101st Cong., 2d sess. 31 (1990).) Expedited hearing procedures under section 513(e) of the act, therefore, would be in accordance with the law. However, FDA believes that most temporary suspension hearings will be conducted within the timeframes set out in part 16.

3. Another comment stated that enacting this rule as proposed, i.e., authorizing FDA to suspend, modify, or waive any part 16 procedures, would create a procedure whereby persons challenging recall orders would have greater opportunities to defend themselves than persons affected by PMA suspension orders.

As noted above, FDA is seeking to make as consistent and parallel as possible the procedures for recalling a device and temporarily suspending approval of a PMA or PMA supplement. Moreover, it is important to point out the additional protections that exist for PMA holders. Under section 515(e)(1) of the act, FDA must provide notice and an opportunity for an informal hearing before issuing an order for permanent withdrawal of PMA or PMA supplement approval. Additionally, a PMA or PMA supplement holder may petition for review of a section 515(e)(1) order pursuant to section 515(g) of the act. Section 515(g)(1) of the act provides ''[u]pon petition for review of * * * an order * * * withdrawing approval of an [PMA] application * * * the Secretary shall * * * hold a hearing * * *. The panel or panels which considered the application * * * shall designate a member to appear and testify at any such hearing upon request of the Secretary, the petitioner, or the officer conducting the hearing * * *. Upon completion of such hearing and after considering the record established in such hearing, the Secretary shall issue an order either affirming the order subject to the hearing or reversing such order and, as appropriate, * * * reinstating the application's approval * * *.'' Thus, a PMA or PMA supplement holder is provided with additional opportunities for a hearing prior to permanent withdrawal of PMA or PMA supplement approval.

4. Another comment suggested that FDA's reliance upon H. Rept. 808, 101st Cong., 2d sess. 31 for authority to give notice, conduct a hearing, and render a judicial decision within 1 day is misplaced because this legislative history relates to hearings, not informal hearings.

FDA disagrees with this comment. The hearing referred to in the legislative history clearly pertains to the informal hearing discussed in section 515(e)(3) of the act even though Congress used the term ''hearing,'' rather than ''informal hearing'' in the legislative history. Moreover, FDA can give notice, conduct a hearing, and render a decision in 1 day and still satisfy the informal hearing requirements found in section 201(x) of the act. However, as discussed in response to comment 2 of this document, FDA anticipates that temporary suspension hearings will almost always be conducted in accordance with the timeframes set out in part 16.

5. A comment suggested that there is no need for this rule because FDA can simply request a PMA holder to immediately stop distributing the product or, if a PMA holder fails to comply with this request, FDA can issue an order under FDA's recall authority to stop distribution of a device which threatens the public health.

FDA disagrees with this comment. Congress gave FDA two separate, though overlapping, authorities to remove dangerous devices from the market. FDA will use one or both of these mechanisms, depending upon particular circumstances. As noted earlier, FDA has made the two procedures as consistent and parallel as possible in order to minimize confusion should both authorities be invoked.

6. All comments noted that proposed § 814.47(d) failed to define the term ''proceed expeditiously'' and requested that the final rule specify a timeframe within which FDA must initiate permanent withdrawal of PMA approval after issuing an order temporarily suspending PMA approval. The comments suggested that FDA begin the permanent withdrawal proceedings within 10 to 30 days after issuing the temporary suspension order and conclude the proceedings within 30 to 60 days after issuing the temporary suspension order.

FDA agrees with the goal expressed in these comments. FDA has concluded that following the issuance of an order temporarily suspending approval of a PMA or PMA supplement, the agency will proceed expeditiously, but within 60 days, to hold a hearing on whether to permanently withdraw approval of the PMA or PMA supplement. Based on prior experience, FDA has determined that 60 days is sufficient time for both a PMA holder and FDA to prepare for an informal hearing which is required to be held prior to permanently withdrawing approval of a PMA, if such a hearing is requested. Section 814.14(d) has been amended accordingly.

7. A comment requested that the ''serious, adverse health consequences'' definition found in proposed § 814.3 be changed. It was suggested that the words ''long range'' be replaced with ''long term'' because ''long term'' is a phrase that is more precise, that conforms to the legislative history, and that is more familiar to medical device manufacturers. (See S. Rept. 513, 101st Cong., 2d sess. 19 (1990).)

FDA agrees with this comment. The legislative history surrounding section 515(e)(3) of the act states that the term ''serious, adverse health consequences'' means: any significant adverse experience attributable to a device, including those which may be either life-threatening, or involve permanent or long-term injuries, but excluding those nonlife-threatening injuries which are temporary and reasonably reversible. (See S. Rept. 513, 101st Cong., 2d sess. 19 (1990).) The definition has been changed to reflect the legislative history definition.

FDA also has revised the definition of serious, adverse health consequences in § 814.3(l) by deleting the following sentence: ''Injuries attributable to a device that are treatable and reversible by standard medical techniques, proximate in time to the injury, are not included within the term's definition.'' The legislative history makes clear that the idea captured in the second sentence of the proposed definition was intended only to further explain the type of injury that would trigger temporary suspension *Id*. FDA has made the same revision in the medical device recall regulation.

8. One comment said that the preamble to the proposed rule suggested that application of section 515(e)(3) of the act turns on the judgment of whether, if distribution of the devices continues, one or more individual devices would be more likely than not to cause serious, adverse health consequences or death. The comment stated that this statement in the preamble erroneously implies that one device is enough to allow FDA to order a temporary PMA suspension.

FDA believes this comment misunderstands FDA's intent. FDA emphasizes that application of section 515(e)(3) of the act does not turn on whether a particular percentage of devices would cause serious, adverse health consequences or death, but rather on the judgment of whether it is more likely than not that serious, adverse health consequences or death will result if distribution of the device continues.

9. A comment urged that the definition of ''reasonable probability'' found in proposed § 814.3 be made consistent with the February 1988 CDRH Medical Device Reporting Questions and Answers document, p. 22, for reportable malfunctions, which defines ''likely'' in terms of both a qualitative and quantitative evaluation of the likelihood that a recurrence of the malfunction will cause or contribute to a death or serious injury.

FDA disagrees with this comment. The legislative history of section 515(e)(3) of the act states that a ''reasonable probability'' is ''one where it is more likely than not that the event will occur.'' (See S. Rept. 513, 101st Cong., 2d sess. 19 (1990).) The same ''reasonable probability'' definition has been incorporated in § 814.3(k) for consistency.

10. A comment requested that the rule allow a manufacturer to voluntarily withdraw a product before FDA issues an order temporarily suspending approval of the PMA.

FDA agrees that a manufacturer can voluntarily withdraw a PMA or PMA supplement before FDA issues an order temporarily suspending approval of the application. In fact, FDA will ordinarily encourage the manufacturer to voluntarily withdraw its application before FDA issues a temporary suspension order. However, if FDA's attempts are unsuccessful or if FDA chooses not to urge voluntary withdrawal initially, FDA will follow the procedures for temporarily suspending approval of the manufacturer's PMA or PMA supplement. Because a voluntary withdrawal of the application renders moot the need for FDA to suspend its approval, there is no need to include this procedure in the final rule.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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 nor an environmental impact statement is required.

VIII. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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. Because this rule only establishes the procedures by which FDA will implement its authority for the temporary suspension of approval of premarket approval applications, by

itself it imposes no burdens on manufacturers. Thus, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 814 is amended as follows:

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

1.The authority citation for 21 CFR part 814 continues to read as follows:

Authority: Secs. 501, 502, 503, 510, 513–520, 701, 702, 703, 704, 705, 708, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381).

2. Section 814.3 is amended by adding new paragraphs (k) and (l) to read as follows:

§ 814.3 Definitions.

* * * * *

(k) *Reasonable probability* means that it is more likely than not that an event will occur.

(l) *Serious, adverse health consequences* means any significant adverse experience, including those which may be either life-threatening or involve permanent or long term injuries, but excluding injuries that are nonlife-threatening and that are temporary and reasonably reversible.

3. New § 814.47 is added to subpart C to read as follows:

§ 814.47 Temporary suspension of approval of a PMA.

(a) *Scope.* (1) This section describes the procedures that FDA will follow in exercising its authority under section 515(e)(3) of the act (21 U.S.C. 360e(e)(3)). This authority applies to the original PMA, as well as any PMA supplement(s), for a medical device.

(2) FDA will issue an order temporarily suspending approval of a PMA if FDA determines that there is a reasonable probability that continued distribution of the device would cause serious, adverse health consequences or death.

(b) *Regulatory hearing.* (1) If FDA believes that there is a reasonable probability that the continued distribution of a device subject to an approved PMA would cause serious, adverse health consequences or death, FDA may initiate and conduct a regulatory hearing to determine whether to issue an order temporarily suspending approval of the PMA.

(2) Any regulatory hearing to determine whether to issue an order temporarily suspending approval of a PMA shall be initiated and conducted by FDA pursuant to part 16 of this chapter. If FDA believes that immediate action to remove a dangerous device from the market is necessary to protect the public health, the agency may, in accordance with § 16.60(h) of this chapter, waive, suspend, or modify any part 16 procedure pursuant to § 10.19 of this chapter.

(3) FDA shall deem the PMA holder's failure to request a hearing within the timeframe specified by FDA in the notice of opportunity for hearing to be a waiver.

(c) *Temporary suspension order.* If the PMA holder does not request a regulatory hearing or if, after the hearing, and after consideration of the administrative record of the hearing, FDA determines that there is a reasonable probability that the continued distribution of a device under an approved PMA would cause serious, adverse health consequences or death, the agency shall, under the authority of section 515(e)(3) of the act, issue an order to the PMA holder temporarily suspending approval of the PMA.

(d) *Permanent withdrawal of approval of the PMA.* If FDA issues an order temporarily suspending approval of a PMA, the agency shall proceed expeditiously, but within 60 days, to hold a hearing on whether to permanently withdraw approval of the PMA in accordance with section 515(e)(1) of the act and the procedures set out in § 814.46.

Dated: March 28, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–8361 Filed 4–4–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 21

RIN 2900–AH14

Veterans Education: Increase in Rates Payable Under the Montgomery GI Bill—Active Duty, 1994–95

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: By statute the monthly rates of basic educational assistance payable to veterans and servicemembers under the Montgomery GI Bill —Active Duty must be adjusted each fiscal year. In accordance with the statutory formula, the regulations governing rates of basic educational assistance payable under the Montgomery GI Bill—Active Duty for fiscal year 1995 (October 1, 1994 through September 30, 1995) are changed to show a 1.22% increase.

EFFECTIVE DATE: April 5, 1996.

FOR FURTHER INFORMATION CONTACT: June C. Schaeffer, Assistant Director for Policy and Program Administration, Education Service, Veterans Benefits Administration (202) 273–7187.

SUPPLEMENTARY INFORMATION: Under the formula mandated by 38 U.S.C. 3015(g) and section 12009 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) for fiscal year 1995, the rates of basic educational assistance under the Montgomery GI Bill—Active Duty payable to students pursuing a program of education full time must be increased by one-half of the percentage that the total of the monthly Consumer Price Index-W for July 1, 1993 through June 30, 1994 exceeds the total of the monthly Consumer Price Index-W for July 1, 1992 through June 30, 1993. Under this formula, the changes to the regulations governing monthly rates reflect a 1.22% increase.

It should be noted that some veterans will receive an increase in monthly payments that will be less than 1.22%. The increase does not apply to additional amounts payable by the Secretary of Defense to individuals with skills or a specialty in which there is a critical shortage of personnel (so-called ''kickers''). It does not apply to supplemental educational assistance. It also does not apply to amounts payable for dependents. Veterans who previously had eligibility under the Vietnam Era GI Bill receive monthly payments that are in part based upon basic educational assistance and in part based upon the rates payable under the Vietnam Era GI Bill. Only that portion attributable to basic educational assistance is increased by 1.22%.

Although 38 U.S.C. 3015(g) requires only that the full-time rates be increased, these revisions include increases for other training also. Monthly rates payable to veterans in apprenticeship or other on-job training or cooperative training are set by statute at a given percentage of the full-time rate. Hence, any rise in the full-time rate