DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority to reflect a new delegation that authorizes the Division Directors, Office of Device Evaluation (ODE), Center for Devices and Radiological Health (CDRH) to approve, disapprove, or withdraw approval of product development protocols and applications for premarket approval for medical devices. As a result of reengineering initiatives within CDRH, for the Premarket Approval and Product Development Protocol Programs, this delegation will improve the efficiency of operations for these programs. These authorities will not be further redelegated at this time.

EFFECTIVE DATE: May 18, 1998.

FOR FURTHER INFORMATION CONTACT: Debra A. Baclawski, Center for Devices and Radiological Health (HFZ-026), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–1060, or Donna G. Page, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1988.

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:


2. Section 5.53 is amended by revising paragraphs (a)(1) and (b)(1)(i) to read as follows:

§ 5.53 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.

(a) * * *

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH, and the Division Directors, ODE, CDRH.

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(b)(1) * * *
DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 507

Manufacture, Sale, Wear, Commercial Use and Quality Control of Heraldic Items

AGENCY: Department of the Army, DoD.

ACTION: Final rule.

SUMMARY: This revision authorizes the manufacture and sale of full size military medals and decorations. In the past the manufacture and sale of these items was prohibited except under Government contract through the Defense Personnel Support Center. In coordination with all the Services, the Office of the Secretary of Defense approved the manufacture and sale of full size military medals and decorations with the provision that no version of the Medal of Honor can be manufactured except under Government contract with the Defense Personnel Support Center. This rule also revises the Department of the Army policy (Army Regulation 672–8) governing the manufacture and quality. The revision was previously announced in the proposed rule section of the Federal Register, Vol. 63, No. 47, Pages 11858–11862, Wednesday, March 11, 1998 for public comment.

b. Comments and Responses

No comments were received on the proposed rule.

Executive Order 12866

This rule is not a major rule as defined by Executive Order 12866.

Regulatory Flexibility Act

The Regulatory Flexibility Act has no bearing on this rule.

Paperwork Reduction Act

This rule does not contain reporting or record keeping requirements subject to the Paperwork Reduction Act.

List of Subjects in 32 CFR Part 507

Decorations, Medals, Awards.

Accordingly, 32 CFR Part 507 is revised to read as follows:

PART 507—MANUFACTURE AND SALE OF DECORATIONS, MEDALS, BADGES, INSIGNIA, COMMERCIAL USE OF HERALDIC DESIGNS AND HERALDIC QUALITY CONTROL PROGRAM

Subpart A—Introduction

Sec.
507.1 Purpose.
507.2 References.
507.3 Explanation of abbreviations and terms.
507.4 Responsibilities.
507.5 Statutory authority.

Subpart B—Manufacture and sale of Decorations, Medals, Badges, and Insignia

507.6 Authority to manufacture.
507.7 Authority to sell.
507.8 Articles authorized for manufacture and sale.
507.9 Articles not authorized for manufacture or sale.

Subpart C—Commercial Use of Heraldic Designs

507.10 Incorporation of designs or likenesses of approved designs in commercial articles.
507.11 Reproduction of designs.
507.12 Possession and wearing.

Subpart D—Heraldic Quality Control Program

507.13 General.
507.14 Controlled heraldic items.
507.15 Certification of heraldic items.
507.16 Violations and penalties.
507.17 Procurement and wear of heraldic items.
507.18 Processing complaints of alleged breach of policies.


Subpart A—Introduction

§ 507.1 Purpose.

This part prescribes the Department of the Army and the Air Force policy governing the manufacture, sale, reproduction, possession, and wearing of military decorations, medals, badges, and insignia. It also establishes the Heraldic Item Quality Control Program to improve the appearance of the Army and Air Force by controlling the quality of heraldic items purchased from commercial sources.

§ 507.2 References.

Related publications are listed in paragraphs (a) through (f) of this section. (A related publication is merely a source of additional information. The user does not have to read it to understand this part). Copies of referenced publications may be reviewed at Army and Air Force Libraries or may be purchased from the National Technical Information Services, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161.

(a) AFI 36–2903, Dress and Personal Appearance of Air Force Personnel.
(b) AR 360–5, Public Information.
(c) AR 670–1, Wear and Appearance of Army Uniforms and Insignia.
(d) AR 840–1, Department of the Army Seal, and Department of the Army Emblem and Branch of Service Plaques.
(e) AR 840–10, Heraldic Activities, Flags, Guidons, Streamers, Tabards and Automobile Plates.
(f) AFR 900–3, Department of the Air Force Seal, Organizational Emblems, Use and Display of Flags, Guidons, Streamers, and Automobile and Aircraft Plates.

§ 507.3 Explanation of abbreviations and terms.

(a) Abbreviations.
(1) AFB—Air Force Base.
(2) DA—Department of the Army.