ENTRANCE BETWEEN 20TH AND 21ST STREETS, N.W., WASHINGTON, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: August 10, 1990.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 90-19224 Filed 8-10-90; 2:56 pm]

BILLING CODE 6210-01-M

INTERNATIONAL TRADE COMMISSION

[USITC SE-90-18]

TIME AND DATE: Tuesday, August 21, 1990 at 10:30 a.m.

PLACE: Room 101, 500 E Street, S.W., Washington, D.C. 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda.

2. Minutes.

3. Ratification.

4. Petitions and Complaints: Certain Internal Mixing Devices and Components Thereof (D/N 1577).

5. Inv. No. 731-TA-465-468 (P) (Certain Sodium Sulfur Chemical Compounds from the Federal Republic of Germany, the People's Republic of China, Turkey and the United Kingdom)—briefing and vote.

6. Any items left over from previous agenda.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 252-1000.

Kenneth Mason,

Secretary.

August 7, 1990.

[FR Doc. 90-19184 Filed 8-10-90; 12:09 pm]

BILLING CODE 7020-02-M

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of August 13, 20, 27, and September 3, 1990.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of August 13

Thursday, August 16

8:30 a.m.—Collegial Discussion of Items of Commissioner Interest (Public Meeting)

9:30 a.m.—Affirmative/Discussion and Vote (Public Meeting)

a. Final 1990 Waste Confidence Decision and Amendments to 10 CFR part 51

b. Final Rule on Informal Procedures for Reactor Operator and Senior Reactor Operator Licensing Ajudications (Tentative)

Week of August 27 (Tentative)

There are no meetings scheduled for the week of August 20.

Week of August 30 (Tentative)

Thursday, August 30

11:30 a.m.—Affirmative/Discussion and Vote (Public Meeting) (if needed)

Week of September 3 (Tentative)

There are no meetings scheduled for the week of September 3.

Note.—Affirmative sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

To verify the status of meetings call (Recording)—(301) 492-0292.

CONTACT PERSON FOR MORE INFORMATION: William Hill (301) 492-1661.

William M. Hill, Jr.,

Office of the Secretary

[FR Doc. 90-19221 Filed 8-10-90; 2:55 pm]

BILLING CODE 7590-01-M

Corrections

Federal Register
Vol. 55, No. 157
Tuesday, August 14, 1990

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1005

[Docket Nos. AO-388-A1; AO-388-A1-RO1; DA-88-123]

Milk in the Carolina Marketing Area; Order Regulating the Handling of Milk

Correction

In rule document 90-17803 beginning on page 31351 in the issue of Thursday, August 2, 1990, the CFR line should have appeared as set forth above.

BILLING CODE 1505-01-D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP87-62-006]

Pacific Gas Transmission Co.; Compliance Filing

Correction

In notice document 90-18363 beginning on page 32130, in the third column, in the issue of Tuesday, August 7, 1990, the docket number should read as set forth above.

BILLING CODE 1505-01-D

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 22

[CC Docket No. 88-135; FCC 90-255]

Height and Power Increases in the Public Mobile Service

Correction

In rule document 90-17390 beginning on page 30461 in the issue of Thursday, July 26, 1990, make the following correction:

§ 22.503 [Corrected]

On page 30462, in the second column, after the table and its footnotes insert the following:

"4. Section 22.503 is amended by revising paragraph (d) to read as follows:

§ 22.503 Geographic separation of co-channel stations."

BILLING CODE 1505-01-D

federal register

Tuesday
August 14, 1990

Part II

Department of Defense

48 CFR Parts 202 et al.

Department of Defense Acquisition Regulations; Miscellaneous Amendments; Proposed Rule

DEPARTMENT OF DEFENSE

48 CFR Parts 202, 203, 207, 219, 220, 224, 226, 229, 231, 233, 243, 248, 250, 251, 252, and Appendix Q

Department of Defense Acquisition Regulations; Miscellaneous Amendments

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule with request for comments.

SUMMARY: The Defense Federal Acquisition Regulation Supplement (DFARS) is being rewritten in its entirety as a result of a Defense Management Review initiative. The rewrite is designed to: eliminate text and clauses that are unnecessary (e.g., duplicate FAR or other directives, add no value, etc.); eliminate or modify, where possible, thresholds, certifications, approval levels, and other regulatory burdens on contracting officers and contractors; and rephrase remaining text and clauses in plain English. The rewrite will be published for public comment in four increments. This is the first increment.

DATES: Comments must be submitted on or before October 15, 1990.

ADDRESSES: Interested parties should submit written comments to: Defense Acquisition Regulatory Council, ATTN: Ms. Lucile Hughes, DAR Council, ODASD(P)/DARS, c/o OASD(P&L)(M&RS), room 3D139, Pentagon, Washington, DC 20301–3062. Please cite DAR Case 90–743 in all correspondence concerning this proposed rule.

FOR FURTHER INFORMATION CONTACT: 202–697–7266, Valorie Lee, for parts 202, 203, 248; Barbara Young, for part 207; Alyce Sullivan, for parts 219, 220, 224, 226, 229, Appendix Q; Eric Mens, for parts 231, 233, 250, 251; and Charles Lloyd, for part 243.

SUPPLEMENTARY INFORMATION:

A. Background

The Secretary of Defense's July 1989 Defense Management Report to the President concluded that much of the stifling burden of DoD regulatory guidance, including the Defense Federal Acquisition Regulation Supplement (DFARS), is self-imposed. To correct this situation, the DoD formed a Regulatory Relief Task Force to review DFARS and lower level supplements and to recommend revisions. As a result, the Defense Acquisition Regulatory System, under the direction of the Deputy Assistant Secretary of Defense for Procurement, has undertaken the complete rewrite of DFARS. The rewrite is designed to: Eliminate text and clauses that are unnecessary (e.g., duplicate FAR or other directives, add no value, etc.); eliminate or modify, where possible, thresholds, certifications, approval levels, and other regulatory burdens on contracting officers and contractors; and rephrase remaining text and clauses in plain English.

The rewritten DFARS is being published for public comment in four monthly increments. This publication of DFARS parts 202, 203, 207, 219, 220, 224, 226, 229, 231, 233, 243, 248, 250, 251, and their attendant clauses in part 252 is the first increment. All public comments received in response to this notice will be considered in developing the final rule, which is planned for publication in February 1991. Parties responding to this notice are requested to separate their comments by DFARS part.

The rewritten DFARS is addressed to the contracting officer. Every attempt has been made to remove extraneous material which, though informative, was guidance addressed to others in the acquisition process, e.g., program managers, requirements personnel, small business specialists, etc. Text which was unnecessary or redundant has been removed. Some text has been moved to the FAR and some additional text in this proposed rule may be moved to the FAR before the rule is finalized. Text has been rearranged, and in some instances, moved to other parts, to more closely align the DFARS text with the FAR text it implements or supplements. The rewritten DFARS includes some policy and procedural changes. These are identified in the following discussion of revisions by part. Unless specifically identified as a change, the rewritten version of the part is not intended as a change in current policy or procedure.

Part 202, Definitions of Words and Terms. The definitions of "Department" and "Head of the Agency" have been deleted. The remaining definitions have been revised and updated. A definition of "Contracting officer's representative" has been added.

Part 203, Improper Business Practices and Personal Conflicts of Interest. Several definitions in the text have been moved to clauses. Some definitions have been deleted from the clauses. The clause at 252.203–7000, Advertising and Coupon Redemption for Military Resale Activities, has been deleted. This clause was considered an inappropriate vehicle for enforcement of the prohibition against implying Government endorsement of a product. The clause at 252.203–7002, Statutory Compensation Prohibitions and Reporting Requirements Relating to Certain Former Department of Defense Employees, has been retitled and renumbered as 252.203–7000. The clause at 252.203–7003, Display of DoD Hotline Poster, has been renumbered as 252.203–7002.

Part 207, Acquisition Planning. The thresholds at 207.103(c) for requiring written acquisition plans have been increased. The requirement at 207.304 for the contracting officer to work in conjunction with the functional activity in preparation of performance work statements has been deleted, leaving this to the discretion of the contracting officer.

Part 219, Small Business and Small Disadvantaged Business Concerns. This part has been substantively revised—by clarifying responsibilities; by eliminating conflicting guidance; by tying the small business specialist's responsibilities to specific functions; and by removing impediments to contracting with small businesses. Specifically, (1) The DoD order of precedence for set-asides (DFARS 219.504) has been reconciled with the FAR order of precedence. (2) The requirement, associated with small disadvantaged business set-asides (DFARS 219.502–72(c)), for specific analysis of offers received on prior acquisitions has been eliminated. (3) The contracting officer has been given approval authority to proceed in face of Secretarial appeal (DFARS 219.505(f)). (4) File documentation requirements associated with premium payments (DFARS 219.202–5(b)) and resolution of disagreements (DFARS 219.505(a)(2)) have been eliminated. (5) Mandatory coordination requirements have been modified/eliminated: processing SBA requests (DFARS 219.402(b)); withdrawal of class set-asides (DFARS 219.503(d)); withdrawal of other set-asides (DFARS 219.506(b)); and determination that there are no small disadvantaged business manufacturers (DFARS 219.7002). (6) Both the small business specialist's and the contracting officer's responsibilities for the review of acquisitions have been clarified. Review of all acquisitions over $25,000 must be documented on a new DD Form, which is to replace the individual forms currently in use by the military departments and agencies. (7) This proposed rule also includes those revisions published in the **Federal Register** April 17, 1990 (55 FR 14329) for public comment, i.e., deletion of combined small business-labor surplus area set-asides. (8) The clauses have been rewritten/modified/deleted/combined as follows:

252.219–7000 Includes a new definition of "minority institution" (see part 226 explanation)
252.219–7001 Deleted
252.219–7002 Deleted
252.219–7003 Deleted
252.219–7004 Combined with the proposed 252.219–7004
252.219–7005 Retitled and renumbered as 252.219–7001
252.219–7006 Retitled and renumbered as 252.219–7002
252.219–7007 Retitled and renumbered as 252.219–7003
252.219–7009 Retitled and renumbered as 252.219–7005
252.219–7010 Renumbered as 252.219–7004
252.219–7011 Combined with the proposed 252.219–7004
252.219–7012 Deleted—moved to FAR
252.219–7013 Deleted—moved to FAR
252.219–7014 Deleted—moved to FAR
252.219–7015 Renumbered as 252.219–7006
252.219–7016 Renumbered as 252.219–7007

Part 220, Labor Surplus Area Concerns. The deletion of part 220 was published in the **Federal Register** as a proposed rule for public comment on March 22, 1990 (55 FR 10637), as amended April 6, 1990 (55 FR 12870). The deletion of the clauses at 252.220–7000 and 252.220–7001 was published April 6, 1990 (55 FR 12870).

Part 224, Protection of Privacy and Freedom of Information. No changes in policy or procedure. This part is exactly the same as the final rule published in Defense Acquisition Circular 88–15, which appeared as a final rule in the **Federal Register** on July 24, 1990 (55 FR 30154). That rule deleted DFARS Appendix L and Appendix P.

Part 226, Other Socioeconomic Programs. The definitions of "historically black college and university" and "minority institution" have been moved from DFARS subpart 226.70 to the clauses at 252.226–7000 and 252.226–7001. The definition of "minority institution" has been revised to conform to the definition prescribed by section 806 of Public Law 100–180.

Part 229, Taxes. The requirement in DFARS 229.303(a)(2), for referral to the Under Secretary of Defense (R&E) of cases designating a contractor an agent of the Government for purposes of immunity from State or local taxes, is deleted. The clause at 252.229–7000, Fixed-Price, Into-Plane, Fuel Contracts at Overseas Locations, has been deleted as no longer necessary or useful. Appendix Q, which is a reprint of DoDD 5100.64, Foreign Tax Relief Program, has been deleted.

Part 231, Contract Cost Principles and Procedures. The clauses at 252.231–7001, Supplemental Cost Principles, and 252.231–7002, Penalties for Unallowable Costs, have been combined into one clause.

Part 233, Protests, Disputes, and Appeals. The reference to section 813 of Public Law 95–485 has been removed from DFARS subpart 233.70 but the certification requirement in subpart 233.70 and the contract clause at 252.233–7000, Certification of Requests for Adjustment or Relief Exceeding $100,000, have been retained.

Part 243, Contract Modifications. Text has been moved from DFARS part 243 to other parts: 243.105, Availability of funds, moved to DFARS 232.7; 243.204(S–73), Modifications to letter contracts, moved to DFARS 204.101(a); 243.7001, Adjustments to prices under shipbuilding contracts, moved to DFARS 233.210.

Part 248, Value Engineering. The requirement in DFARS 248.201(a), for inclusion of a value engineering incentive clause in contracts of $25,000 or more for spare parts and repair kits, has been deleted. A clause has been added at DFARS 252.248–7000, Preparation of Value Engineering Change Proposals, for use in specifying use of the format in MIL STD 480 or 481.

Part 250, Extraordinary Contractual Actions. No changes in policy or procedure.

Part 251, Use of Government Sources by Contractors. No changes in policy or procedure.

Part 252, Solicitation Provisions and Contract Clauses. Revisions in provisions/clauses are identified in the discussion of the part which prescribes use of the provision or clause.

B. Regulatory Flexibility Act

Parts 202, 203, 207, 224, 229, 231, 233, 243, 248, 250, 251 and the provisions/clauses in part 252 prescribed by these parts. These proposed rules do not constitute significant revisions within the meaning of Public Law 98–577; therefore, the Regulatory Flexibility Act does not apply.

Parts 219 and the provisions/clauses in part 252 prescribed by part 219. These proposed rules are not expected to have a significant economic impact on a substantial number of small entities because the basic policies remain unchanged and with few exceptions, the procedural changes are internal agency operating procedures. An Initial Regulatory Flexibility Analysis has not been performed. Comments are solicited from small business and other interested parties and will be considered in development of the final rule.

Part 220 and the clauses in part 252 prescribed by part 220. The proposed deletion of part 220 and the clauses in 252.220–7000 and 252.220–7001 was published in the **Federal Register** for public comment on March 22, 1990 (55 FR 10637), as amended April 6, 1990 (55 FR 12870). An Initial Regulatory Flexibility Analysis was not performed because we were unable to quantify the economic impact on small entities.

Part 226 and the provision and clause in part 252 prescribed by part 226. These proposed rules are not expected to have a significant economic impact on a substantial number of small entities because, with one exception, the basic policies and procedures are unchanged. The change in the definition of "minority institution" will affect approximately 600 educational institutions but is not expected to have an impact on small businesses. An Initial Regulatory Flexibility Analysis has not been performed but comments received will be considered in development of the final rule.

C. Paperwork Reduction Act

Parts 202, 203, 207, 224, 226, 231, 233, 243, 248, 250, 251, and the provisions/clauses in part 252 prescribed by these parts. These proposed rules do not change or impose any record keeping or information collection requirements beyond that for which OMB approval has previously been obtained.

Part 219 and the provisions/clauses in part 252 prescribed by part 219. This proposed rule does not contain information collection requirements which require the approval of OMB under 44 U.S.C. 3501, et seq. The rule results in a reduction of 402 hours based on the deletion of the combined small business-labor surplus area setasides (DFARS 219.502–70 and the clauses at 252.219–7001 and 252.219–7002). This requirement is currently approved under OMB control number 0704–0218. A request for paperwork clearance has been prepared based on the deletion of the requirement associated with combined small business-labor surplus area set-asides.

Part 220 and the clauses in part 252 prescribed by part 220. This proposed rule does not contain information collection requirements which require the approval of OMB under 44 U.S.C. 3501, et seq. The rule results in a reduction of 201 hours. This requirement is currently approved under OMB control number 0704–0260. A request for paperwork clearance has been prepared.

Part 229 and the clause in 252.229–7000. This proposed rule does not contain information collection requirements which require approval of OMB under 44 U.S.C. 3501, et seq. Record keeping/reporting requirements imposed by the clause at DFARS 252.229–7000 are currently approved under OMB control number 0704–0249.

Deletion of this clause results in a reduction of 372 hours. A request for paperwork clearance has been prepared.

List of Subjects in 48 CFR Parts 202, 203, 207, 219, 220, 224, 226, 229, 231, 233, 243, 248, 250, 251, and 252

Government procurement.

Claudia L. Naugle,

Executive Editor, Defense Acquisition Regulatory Council.

Adoption of Amendments

Therefore, it is proposed that 48 CFR parts 202, 203, 207, 219, 220, 224, 226, 229, 231, 233, 243, 248, 250, 251, and 252 be amended as follows:

1. Part 202 is revised to read as follows:

PART 202—DEFINITIONS OF WORDS AND TERMS

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

Subpart 202.1—Definitions

202.101 Definitions.

Contracting activity. For the DoD, the designated elements are as follows:

Office of the Secretary of Defense

Strategic Defense Initiative Organization-Director
Washington Headquarters Service-Director, Real Estate and Facilities Directorate

Army

Contract Support Agency
Office of the Deputy Chief of Staff for Procurement, Headquarters, U.S. Army Materiel Command
Armament Munitions and Chemical Command
Missile Command
Laboratory Command
Communications-Electronics Command
Troop Support Agency
Troop Support Command
Tank-Automotive Command
Aviation Systems Command
Training and Doctrine Command
Test and Evaluation Command
Forces Command
Health Services Command
Military District of Washington
U.S. Army, Europe
National Guard Bureau
Corps of Engineers
Information Systems Command
Medical Research and Development Command
Western Command
Military Traffic Management Command
Strategic Defense Command
Eighth U.S. Army
Depot Systems Command
Intelligence and Security Command
U.S. Army, South
Defense Supply Service-Washington, Director

Navy

Deputy for Acquisition Policy, Integrity and Accountability, Office of the Assistant Secretary of the Navy (Research, Development, and Acquisition)
Director, Procurement Policy
Naval Air Systems Command
Space and Naval Warfare Systems Command
Naval Facilities Engineering Command
Naval Sea Systems Command
Naval Supply Systems Command
Ships Parts Control Center
Navy Aviation Supply Office
Office of Naval Research
Military Sealift Command
Strategic Systems Programs
Headquarters, U.S. Marine Corps
U.S. Marine Corps Research, Development, and Acquisition Command
Installations and Logistics, Headquarters, U.S. Marine Corps

Air Force

Headquarters, Directorate of Contracting and Manufacturing Policy
Air Force Logistics Command
Air Force Systems Command
Strategic Air Command
Tactical Air Command
Air Force Communications Command
Military Airlift Command
Air Training Command
Pacific Air Forces
United States Air Forces in Europe
Alaskan Air Command
Space Command
Electronic Security Command

Defense Logistics Agency

Office of the Executive Director, Contract Management
Office of the Executive Director, Contracting
Defense Supply Centers
Defense Personnel Support Center

Defense Communications Agency

Headquarters
Defense Commercial Communications Office

Defense Mapping Agency

Headquarters, Logistics Office

Defense Nuclear Agency

Headquarters, Defense Nuclear Agency

National Security Agency

Headquarters, National Security Agency

Contracting officer's representative means an individual designated and authorized in writing by the contracting officer to perform specific technical or administrative functions.

Department of Defense (DoD) means the Office of the Secretary of Defense, the Military Departments, the Defense Agencies, and the Strategic Defense Initiative Organization.

Senior procurement executive is now titled *Senior acquisition executive.* For the DoD, these are:

Office of the Secretary of Defense—Under Secretary of Defense (Acquisition)
Army—Assistant Secretary of the Army (Research, Development, and Acquisition)
Navy—The Assistant Secretary of the Navy (Research, Development, and Acquisition)
Air Force—The Assistant Secretary of the Air Force (Acquisition)
Defense Logistics Agency—The Deputy Director (Acquisition Management)
Defense Communications Agency—The Deputy Director, Acquisition Management
Defense Mapping Agency—The Director of Acquisition
Defense Nuclear Agency—The Director, Acquisition Management
National Security Agency—The Deputy Director, National Security Agency

2. Part 203 is revised to read as follows:

PART 203—IMPROPER BUSINESS PRACTICES AND PERSONAL CONFLICTS OF INTEREST

Subpart 203.1—Safeguards

Sec.
203.103 Independent pricing.
203.103–2 Evaluating the certification.
203.104 Procurement integrity.
203.104–1 General.
203.104–4 Definitions.
203.104–5 Disclosure of proprietary and source selection information.
203.104–9 Certification requirements.
203.170 Statutory prohibitions on compensation to former DoD employees.
203.170–1 Policy.
203.170–2 Reporting requirements.
203.170–3 Penalties.
203.170–4 Contract clause.

Subpart 203.2—Contractor Gratuities to Government Personnel

203.203 Reporting suspected violations of the Gratuities clause.

Subpart 203.3—Reports of Suspected Antitrust Violations

203.301 General.

Subpart 203.4—Contingent Fees

203.409 Misrepresentations or violations of the covenant against contingent fees.

Subpart 203.5—Other Improper Business Practices

203.502 Subcontractor kickbacks.
203.502–2 General.
203.570 Employment prohibitions on persons convicted of fraud or other DoD contract-related felonies.
203.570–1 Scope.
203.570–2 Policy.
203.570–3 Waiver.
203.570–4 Reporting.
203.570–5 Contract clause.

Subpart 203.70—Contractor Standards of Conduct

203.7000 Policy.
203.7001 Procedures.
203.7002 Contract clause.

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

Subpart 203.1—Safeguards

203.103 Independent pricing.

203.103-2 Evaluating the certification.

(b)(3) The contracting officer also shall report the matter in accordance with 209.472.

203.104 Procurement integrity.

203.104-1 General.

Military departments and agencies shall submit all regulations that supplement or implement 203.104 or FAR 3.104, except for internal agency operating procedures, to the Deputy Assistant Secretary of Defense (Procurement), for approval by the Under Secretary of Defense (Acquisition) or designee.

203.104-4 Definitions.

(f) For DoD, the agency regulation is DoD Directive 5500.7, Standards of Conduct.

203.104-5 Disclosure of proprietary and source selection information.

(e)(4) For purposes of FAR 3.104-5(e)(4) only, DoD follows the notification procedures in FAR 27.404(h). However, the first sentence in FAR 27.404(h) does not apply to DoD.

203.104-9 Certification requirements.

(b)(2)(viii) For Basic Ordering Agreements (BOAs), prior to issuance of each order expected to exceed $100,000. For BOA orders, identification of the beginning of the conduct of a procurement (see FAR 3.104-7) applies individually to each order.

203.170 Statutory prohibitions on compensation to former DoD employees.

203.170-1 Policy.

10 U.S.C. 2397b prohibits DoD officials who, while serving with the DoD, performed acquisition related functions in connection with a major defense contractor, from accepting compensation from that contractor for a period of two years after the officials have left service with the DoD. The DoD implementation of the statute is in DoD Directive 5500.7, Standards of Conduct.

203.170-2 Reporting requirements.

Paragraph (c) of the clause at 252.203-7000, Statutory Prohibitions on Compensation to Former Department of Defense Employees, requires major defense contractors to report on the employment of certain former DoD employees. (See clause at 252.203-7000 for definition of terms.)

203.170-3 Penalties.

(a) Contractors are subject to the following penalties for knowing failure to comply with the statute, the contractual prohibition, or the reporting requirements—

(1) Civil fines up to $500,000 for knowingly offering or providing compensation to another person with knowledge that acceptance of that compensation is or would be in violation of the statute.

(2) Liquidated damages in the amount of either $100,000 or three times the amount of compensation paid by the contractor to the former DoD official, whichever is greater, for failure to comply with the contract prohibition.

(3) An administrative penalty not to exceed $10,000 for failure to report as required by the statute and as implemented in the clause at 252.203-7000.

(b) Liquidated damages will be assessed in accordance with agency procedures in coordination with the Designated Agency Ethics Official.

203.170-4 Contract clause.

Use the clause at 252.203-7000, Statutory Prohibitions on Compensation to Former Department of Defense Employees, in all solicitations and contracts expected to exceed $100,000.

Subpart 203.2—Contractor Gratuities to Government Personnel

203.203 Reporting suspected violations of the Gratuities clause.

Report suspected violations of the Gratuities clause in accordance with 209.472.

Subpart 203.3—Reports of Suspected Antitrust Violations

203.301 General.

(b) Report suspected antitrust violations in accordance with 209.472.

Subpart 203.4—Contingent Fees

203.409 Misrepresentations or violations of the covenant against contingent fees.

(b) Report suspected fraud or other criminal conduct in accordance with 209.472.

Subpart 203.5—Other Improper Business Practices

203.502 Subcontractor kickbacks.

Report suspected violations of the Anti-Kickback Act in accordance with 209.472.

203.502-2 General.

(h) The DoD Inspector General has designated Special Agents of the following investigative organizations as representatives for conducting inspections and audits under the Anti-Kickback Act of 1986:

(i) U.S. Army Criminal Investigation Command.

(ii) Naval Investigative Service.

(iii) Air Force Office of Special Investigations.

(iv) Defense Cnminal Investigative Service.

203.570 Employment prohibitions on persons convicted of fraud or other DoD contract-related felonies.

203.570-1 Scope.

This subpart prescribes policies and procedures to implement 10 U.S.C. 2408.

203.570-2 Policy.

(a) Contractors shall not knowingly allow a person, convicted after September 29, 1988, of fraud or any other felony arising out of a contract with the DoD, to serve—

(1) In a management or supervisory capacity on any DoD contract or subcontract; or,

(2) On its board of directors; or

(3) As a consultant, agent, or representative.

(b) The period covered by the prohibition in paragraph (a) of this subsection is for five years from the date of conviction.

203.570-3 Waiver.

(a) The contracting officer shall—

(1) Review any request for waiver; and

(2) Deny the request if the contracting officer decides the waiver is not required in the interests of national security; or

(3) Forward the request to the head of the agency or designee if the contracting officer decides the waiver may be in the interest of national security.

(b) The head of the agency or designee shall report all waivers granted, and the reasons for granting the waiver, to the Under Secretary of Defense (Acquisition), who will forward the report to Congress as required by 10 U.S.C. 2408(a)(3).

203.570-4 Reporting.

When a Defense contractor is found in violation of the prohibition in 203.572-2, prepare a report in accordance with agency procedures (see DoD Directive 7050.5).

203.570-5 Contract clause.

Use the clause at 252.203-7001, Special Prohibition on Employment, in all solicitations and contracts, except those which use the small purchase procedures of FAR part 13.

Subpart 203.70—Contractor Standards of Conduct

203.7000 Policy.

Government contractors must conduct themselves with the highest degree of integrity and honesty. Contractors should have standards of conduct and internal control systems that—

(1) Are suitable to the size of the company and the extent of their involvement in Government contracting,

(2) Promote such standards,

(3) Facilitate timely discovery and disclosure of improper conduct in connection with Government contracts, and

(4) Ensure corrective measures are promptly instituted and carried out.

203.7001 Procedures.

(a) A contractor's system of management controls should provide for—

(1) A written code of business ethics and conduct and an ethics training program for all employees;

(2) Periodic reviews of company business practices, procedures, policies, and internal controls for compliance with standards of conduct and the special requirements of Government contracting;

(3) A mechanism, such as a hotline, by which employees may report suspected instances of improper conduct, and instructions that encourage employees to make such reports;

(4) Internal and/or external audits, as appropriate;

(5) Disciplinary action for improper conduct;

(6) Timely reporting to appropriate Government officials of any suspected or possible violation of law in connection with Government contracts or any other irregularities in connection with such contracts; and

(7) Full cooperation with any Government agencies responsible for either investigation or corrective actions.

(b) Contractors who are awarded a DoD contract of $5 million or more must display DoD Hotline Posters prepared by the DoD Office of the Inspector General unless—

(1) The contract will be performed in a foreign country; or

(2) The contractor has established an internal reporting mechanism and program, as described in paragraph (a) of this section.

203.7002 Contract clause.

Use the clause at 252.203-7002, Display of DoD Hotline Poster, in solicitations and contracts expected to exceed $5 million, except when performance will take place in a foreign country.

3. Part 207 is revised to read as follows:

PART 207—ACQUISITION PLANNING

Subpart 207.1—Acquisition Plans

Sec.

Subpart 207.3—Contractor Versus Government Performance

Subpart 207.4—Equipment Lease or Purchase

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

Subpart 207.1—Acquisition Plans

207.103 Agency-head responsibilities.

(c)(i) Military departments and agencies shall prepare written acquisition plans for—

(A) Acquisitions for development, as defined in FAR 35.001, when total contract cost is estimated at $5 million or more; and

(B) Acquisitions for production or services when contract cost is estimated at $30 million for all years or $15 million for any fiscal year.

(C) Any other acquisition considered appropriate by the department or agency.

(ii) Written plans are not required in acquisitions for a final buy out or one-time buy. The terms "final buy out" and "one-time buy" refer to a single contract which covers all known present and future requirements. This exception does not apply to a multiyear contract or a contract with options or phases.

(d) Prepare written acquisition plans meeting the criteria and thresholds of paragraphs (c)(i) (A)and (B) of this section on a system basis. Other acquisition plans may be written on either a system or individual contract basis.

(f) The program manager, or other official responsible for the program, has overall responsibility for acquisition planning.

(h)(i) Apply design-to-cost principles—

(A) In all acquisitions for Major and Non-Major Defense Acquisition Programs (DoDD 5000.1), unless exempted by the Secretary of Defense, and

(B) To the acquisition of systems, subsystems, and components below the thresholds for major defense systems, to the extent prescribed in DoD Directive 4245.3, Design to Cost.

(ii) Consider life-cycle-cost in all acquisitions of systems and equipment.

207.105 Contents of bitten acquisition plans.

For acquisitions covered by 207.103(c)(i) (A) and (B), correlate the plan to the DoD Six Year Defense Program, applicable budget submissions, and the decision coordinating paper/acquisition decision memorandum, as appropriate.

(a) *Acquisition Background and Objectives.* Also include—

(i) Applicability of a decision coordinating paper (DCP), acquisition decision memorandum, Defense Acquisition Board (DAB), and/or internal service reviews. Describe the options in the DCP/acquisition decision memorandum and delineate which option the acquisition plan supports.

(ii) The date approval for operational use has been or will be obtained. If waivers are requested, describe the need for the waivers.

(iii) A milestone chart depicting the acquisition objectives.

(iv) Milestones for updating the acquisition plan. Indicate when the plan will be updated. Program managers should schedule updates to coincide with DAB reviews and the transition from one phase to another (full-scale development to production).

(8) *Acquisition Streamlining.* DoDD 5000.43 contains policy direction on acquisition streamlining. See MIL-HDBK 248 for guidance on streamlining performance requirements, the technical package, and the contract strategy.

(b) *Plan of Action.*

(2) *Competition.* See FAR 6.303-2 for the information required to be included in the acquisition plan if the plan is to be used to support a justification and approval or a determination and findings under FAR part 6.

(5) *Budgeting and Funding.* Include specific references to budget line items and program elements, where applicable, estimated production unit cost, and the total cost for remaining production.

(6) *Product Descriptions.* For development acquisitions, describe the market research efforts planned or undertaken to identify nondevelopmental items, as defined in 210.001, that could satisfy the acquisition objectives.

(12) *Logistics Considerations.*

(i) Describe the extent of integrated logistics support planning to date, including references to approved plans.

(ii) Discuss the mission profile, reliability and maintainability (R&M) program plan, R&M predictions, redundancy, qualified parts lists, parts and material qualification, R&M requirements imposed on vendors, failure analysis, corrective action and feedback, and R&M design reviews and trade-off studies.

(iv) See DoDD 4120.3 for procedures on standardization. See DoDI 4120.19 for procedures on the DoD Parts Control Program, and MIL-STD-965, Parts Control Program, for procedures on the Standardized Military Drawing Program.

(12)(S-70) Describe the extent of Computer-Aided Acquisition and Logistics Support (CALS) implementation (see MIL-STD- 1840A).

(17) *Other Considerations.*

(A) Industrial Preparedness (IP). 10 U.S.C. 2502(a)(1) requires the military department or defense agency to conduct for each major defense acquisition program an analysis of the capabilities of the defense industrial base to develop, maintain, and support the program (see DoDD 4005.1).

(1) Provide the program's IP strategy that assesses the capability of the U.S. industrial base to achieve identified surge and mobilization goals. If no IP strategy has been developed, provide supporting rationale for this position.

(2) If in the IP strategy, the development of a detailed IP plan was determined to be applicable, include the plan by text or by reference. If the development of the IP plan was determined not to be applicable, summarize the details of the analysis forming the basis of this decision.

(3) If the program involves peacetime and wartime hardware configurations which are supported by logistics support plans, identify their impact on the IP plan.

(B) Ensure compliance with DoDD 4210.15, Hazardous Material Pollution Prevention.

207.106 Additional requirements for major systems.

(b)(1)(A) The contracting officer is prohibited by 10 U.S.C. 2305(d)(4)(A) from requiring offers for development or production of major systems that would enable the Government to use technical data to competitively reprocure identical items or components of the system if the item or component were developed exclusively at private expense, unless the contracting officer determines that—

(1) The original supplier of the item or component will be unable to satisfy program schedule or delivery requirements;

(2) Proposals by the original supplier of the item or component to meet mobilization requirements are insufficient to meet the agency's mobilization needs; or

(3) The Government is otherwise entitled to unlimited rights in technical data.

(B) If the contracting officer rnakes a determination under paragraphs (b)(1)(A) *(1)* and *(2)* of this section for a competitive solicitation, 10 U.S.C. 2305(d)(4)(B) requires that the evaluation of items developed at private expense be based on an analysis of the total value, in terms of innovative design, life-cycle costs, and other pertinent factors, of incorporating such items in the system.

Subpart 207.3—Contractor Versus Government Performance

207.302 General.

(d) Agencies shall not convert a commercial activity to performance by a private contractor without having first conducted a full cost comparison which demonstrates that contract performance is more economical unless:

(i) The commercial activity is performed exclusively by military personnel, there is adequate competition and reasonable prices can be obtained from qualified commercial sources, or

(ii) The commercial activity involves 45 or fewer DoD civilian employees (see section 1221, Pub. L. 99-661). When this situation applies, refer to DoDD 4100.5 and DoDI 4100.33 for further guidance.

Subpart 207.4—Equipment Lease or Purchase

207.401 Acquisition considerations.

The requiring activity must prepare and provide the contracting officer with the justification supporting the decision to lease or purchase.

4. Part 219 is revised to read as follows:

PART 219—SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS CONCERNS

Sec.

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

219.000 Scope of part.

This part also implements section 1207 of Public Law 99–661, section 806 of Public Law 100–180, and section 831 of Public Law 101–189. These laws set a goal for DoD for each of fiscal years 1987–1993 to—

(1) Award five percent of contract and subcontract dollars to small disadvantaged business (SDB) concerns, historically black colleges and universities (HBCUs), and minority institutions (MIs) (See part 226 for policy/procedures on HBCU/MIs); and

(2) Maximize the number of such entities in DoD contracting and subcontracting.

219.001 Definitions.

The definition of "small disadvantaged business concern" to be used for DoD contracts is in the provision at 252.219–7001 and is more restrictive than the definition in FAR 19.001.

Subpart 219.2—Policies

219.201 General policy.

(a) The DoD will use the Section 8(a) program, small disadvantaged business set asides and evaluation preferences, advance payments, outreach, and technical assistance to meet its five percent goal for contract and subcontract awards to small disadvantaged businesses.

(c)(9) Contracting activity small and disadvantaged business utilization specialists perform this function by—

(A) Reviewing and making recommendations for all acquisitions over $25,000, except small business-small purchase set-asides;

(B) Making the review before issue of the solicitation or contract modification and documenting it on DD Form XXX, Small Business Coordination Record;

(C) Referring recommendations which have been rejected by the contracting officer to the Small Business Administration procurement center representative. If a representative is not assigned or available, the specialist refers the matter to the specialist's appointing authority.

(d) Contracting and contract administration activities appoint small and disadvantaged business utilization specialists as directed by DoDD 4205.1, DoD Small Business and Small Disadvantaged Business Utilization Programs. Specialists—

(i) Report directly and are responsible only to their appointing authority;

(ii) Make sure that the contracting activity takes the necessary actions to implement small business, historically black college and university/minority institution, and labor surplus area programs;

(iii) Advise and assist contracting activity personnel on all matters which affect small businesses, historically black colleges and universities or minority institutions, and labor surplus area concerns.

219.202 Specific policies.

219.202-1 Encouraging small business participation in acquisitions.

The DoD will maximize the use of small business concerns as planned producers in the Industrial Readiness Planning Program.

219.202-5 Data collection and reporting requirements.

Determine the premium percentage to be entered in Item D4E of the Individual Contract Action Report (DD Form 350), (see 204.671–5) as follows—

(1) For small disadvantaged business or historically black college and university/minority institution set-asides, divide the difference between the fair market price and the award price by the fair market price.

(2) For 219.7000 evaluation preference awards, divide the difference between the low responsive offer and the award price by the low responsive offer.

(3) For 219.502–3 preferential consideration awards, divide the difference between the award price on the non-set-aside portion and the award price on the set-aside portion by the award price on the non-set-aside portion.

Subpart 219.3—Determination of Status as a Small Business

219.301 Representation by the offeror.

(a) A concern must qualify as a small disadvantaged business (SDB) on the date of submission of its offer and at contract award to be eligible for—

(i) Award under a small disadvantaged business set-aside;

(ii) Preferential consideration as an SDB under a partial set-aside; or

(iii) An evaluation preference for SDBs.

(b) The contracting officer shall protest an offeror's representation that it is a small disadvantaged business concern when—

(i) There is conflicting evidence;

(ii) The offeror certifies that the Small Business Administration previously determined the concern to be non-disadvantaged; or

(iii) The offeror represents its ownership as other than Black American, Hispanic American, Native American (including Indian tribes and Native Hawaiian organizations), Asian Pacific American, or Subcontinent Asian American; unless the offeror—

(A) Represents that it currently is in the Section 8(a) program; or

(B) Certifies that—

(1) Within the six months preceding submission of its offer, the offeror was determined by the Small Business Administration to be socially and economically disadvantaged; and

(2) No circumstances have changed to vary that determination.

219.302 Protesting a small business representation.

219.302-70 Protesting a small disadvantaged business representation.

This section applies to protests of a small business concern's status as socially and economically disadvantaged. Protests of a concern's size are processed under FAR 19.302. Any offeror, the contracting officer, or the Small Business Administration (SBA) may protest a concern's representation of disadvantaged status.

(a) An offeror may protest a concern's representation of disadvantaged status by filing a protest with the contracting officer. The protest—

(1) Must be filed within the times specified in FAR 19.302(d)(1); and

(2) Must contain specific detailed evidence supporting the basis of protest.

(b) The contracting officer or the SBA may protest a concern's representation of disadvantaged status at any time.

(1) If a contracting officer's protest is based on information brought to his/her attention by a party ineligible to protest directly or ineligible to protest under the timeliness standard, the contracting officer must be persuaded by the evidence presented before adopting the grounds for protest as his or her own.

(2) The SBA protests a concern's representation of disadvantaged status by filing directly with its Office of Program Eligibility and notifying the contracting officer.

(c) The contracting officer shall return untimely protests to the protestor. This includes protests filed before bid opening or notification of apparent successful offeror.

(d) Upon receipt of a timely protest, the contracting officer shall withhold award and forward the protest to the SBA Office of Program Eligibility, Office of Minority Small Business and Capitol Ownership Development, 1441 L Street, NW., Washington, DC 20416. Send SBA—

(1) The protest;

(2) The date the protest was received and a determination of timeliness;

(3) A copy of the protested concern's self-certification of disadvantaged status; and

(4) The date of bid opening or date on which notification of apparent successful offeror was sent to unsuccessful offerors.

(e) Do not withhold award when—

(1) The contracting officer makes a written determination that award must be made to protect the public interest or

(2) The offeror has certified that—

(i) Within the six months preceding submission of its offer, the SBA has determined the concern to be socially and economically disadvantaged; and

(ii) No circumstances have changed to vary that determination.

(f) The SBA Director, Office of Program Eligibility, will determine the disadvantaged status of the challenged offeror and notify the contracting officer, the challenged offeror, and the protestor. Award may be made on the basis of that determination. The determination is final for purposes of the instant acquisition, unless—

(1) It is appealed; and

(2) The contracting officer receives the appeal decision before award.

(g) If the contracting officer does not receive an SBA determination within 15 working days after the SBA's receipt of the protest, the contracting officer shall presume that the challenged offeror is socially and economically disadvantaged. Do not use the presumption as a basis for award without first inquiring as to when a determination can be expected and waiting for the determination, unless further delay in award would be disadvantageous to the Government.

(h) An SBA determination may be appealed by—

(1) The interested party whose protest has been denied;

(2) The concern whose status was protested; or

(3) The contracting officer.

The appeal must be filed with the SBA's Associate Administrator for Minority Small Business and Capital Ownership Development within five working days after receipt of the determination. If the contracting officer receives the SBA's decision on the appeal before award, the decision shall apply to the instant acquisition. If the decision is received after award, it will apply to future acquisitions.

219.304 Solicitation provisions.

(b) Use the provision at 252.219–7001, Small Disadvantaged Business Concern Representation (DoD Contracts) instead of the provision at FAR 52.219–2, Small Disadvantaged Business Concern Representation.

Subpart 219.5—Set-Asides for Small Business

219.501 General.

(g) This repetitive set-aside procedures applies to DoD.

(S–70) When a product or service has been acquired successfully by a contracting office as a small disadvantaged business set-aside, all future requirements of that office for that product or service shall be acquired as small disadvantaged business set-asides, except those—

(1) Processed under small purchase procedures; or

(2) For which the contracting officer determines there is no reasonable expectation that the criteria for a small disadvantaged business set-aside can be met.

219.502 Setting aside acquisitions.

219.502–1 Requirements for setting aside acquisitions.

Do not set-aside acquisitions for—

(1) Supplies which were developed and financed, in whole or in part, by Canadian sources under the U.S.-Canadian Defense Development Sharing Program; or

(2) Architect-engineer services of $85,000 or more (10 U.S.C. 2855), including indefinite delivery and indefinite quantity contracts if the value of all anticipated orders is expected to total $85,000 or more.

219.502–2 Total set-asides.

(a) Unless the contracting officer determines that the criteria for set-aside cannot be met, set-aside for small business concerns—

(i) Acquisitions for construction, including maintenance and repairs, under $2 million;

(ii) Acquisitions for dredging under $1 million; and

(iii) Acquisitions for architect-engineer services under $85,000.

219.502–270 Total set-asides for small disadvantaged business concerns.

(a) Except as provided in paragraph (b) of this subsection, the contracting officer shall set-aside an acquisition for small disadvantaged businesses when there is a reasonable expectation that—

(1) Offers will be received from at least two responsible small disadvantaged business (SDB) concerns who can comply with the FAR 52.219–14 limitations on subcontracting;

(2) Award will be made at not more than ten percent above fair market price; and

(3) Scientific and/or technological talent consistent with the demands of the acquisition will be offered.

(b) Do not set-aside acquisitions for SDBs when—

(1) The product or service has been successfully acquired as a small business set-aside (see FAR 19.501(g));

(2) The acquisition is for construction, including maintenance and repairs, and is under $2 million, or is for dredging under $1 million;

(3) The acquisition is for architect-engineer services or construction design for military construction projects;

(4) The acquisition is reserved for the 8(a) program;

(5) The acquisition is processed under small purchase procedures; or

(6) The acquisition is for commissary or exchange resale items.

219.502–3 Partial set-asides.

When a portion of an acquisition is to be set aside for small business concerns, the contracting officer shall give small disadvantaged business concerns preferential consideration by using the procedures in 252.219–7004, Notice of Partial Small Business Set-Aside with Preferential Consideration for Small Disadvantaged Business (SDB) Concerns.

219.502–4 Methods of conducting set-asides.

(b) Offers on a small disadvantaged business (SDB) set-aside from concerns that do not qualify as SDB concerns shall be considered nonresponsive and shall be rejected.

219.504 Set-aside program order of precedence.

(b) The order of precedence for DoD is—

(i) Total set-aside for small disadvantaged business concerns;

(ii) Total set-aside for small business concerns;

(iii) Partial set-aside for small business concerns with preferential consideration for small disadvantaged business concerns.

219.505 Rejecting Small Business Administration recommendations.

(b) The designee shall be at a level no lower than chief of the contracting office.

219.506 Withdrawing or modifying set-asides.

(a) Do not withdraw small disadvantaged business set-asides for reasons of price reasonableness unless the low responsive responsible offer exceeds fair market price by more then ten percent.

219.508 Solicitation provisions and contract clauses.

(d)(S–70) Use the clause at 252.219–7004, Notice of Partial Small Business Set-Aside with Preferential Consideration for Small Disadvantaged Business (SDB) Concerns, instead of the clause in FAR 52.219–7, Notice of Partial Small Business Set-Aside. Use the clause with its Alternate I when the contracting officer determines that there are no small disadvantaged business manufacturers that can meet the requirements of the solicitation.

(e) Use this clause also in small disadvantaged business set-asides.

219.508–70 Solicitation provisions and contract clauses.

Use the clause at 252.219–7002, Notice of Small Disadvantaged Business Set-Aside, in solicitations and contracts for small disadvantaged business set-asides. Use the clause with its Alternate I when the contracting officer determines that there are no small disadvantaged business manufacturers that can meet the requirements of the solicitation.

Subpart 219.6—Certificates of Competency and Determinations of Eligibility

219.602 Procedures.

219.602–1 Referral.

When making a nonresponsibility determination on a small business concern, the contracting officer shall notify the contracting activity's small and disadvantaged business utilization specialist.

219.602–3 Resolving differences between the agency and the Small Business Administration.

(c) If the contracting officer believes the agency should appeal, the contracting officer shall send the departmental director of the Office of Small and Disadvantaged Business Utilization, through departmental channels—

(i) A request for appeal, summarizing the issues. The request must be sent to arrive within five working days after receipt of the SBA Central Office's written position.

(ii) An appeal file, documenting the contracting activity's position. The file must be sent to arrive within five working days after transmission of the request.

The departmental director will determine whether the agency will appeal and will notify the SBA of the agency's intent.

Subpart 219.7—Subcontracting With Small Business and Small Disadvantaged Business Concerns

219.702 Statutory requirements.

(a) Section 834 of Pub. L. 101–189 requires the DoD to establish a test program to determine whether comprehensive subcontracting plans on a corporate, division, or plant-wide basis will increase subcontracting opportunities for small business concerns.

(i) The test program—

(A) Will be conducted—

(*1*) Over a three-year period, beginning October 1, 1990.

(*2*) In accordance with the DoD test plan, "Test Program for Negotiation of Comprehensive Small Business Subcontracting Plans."

(*3*) By the military departments and agencies through specifically designated contracting activities.

(B) Permits contractors selected by the designated contracting activities to—

(*1*) Negotiate plant, division, or company-wide comprehensive subcontracting plans instead of individual contract subcontracting plans.

(*2*) Use the comprehensive plans in all DoD contracts which require a subcontracting plan.

(ii) The comprehensive subcontracting plans—

(A) Will be negotiated on an annual basis by the designated contracting activities.

(B) Be incorporated initially by the contractors' cognizant contract administration activity into all of the contractors' active contracts which require a plan.

(C) Be used by all DoD contracting officers in contracts, which require a plan, awarded the selected contractors during the test period.

219.704 Subcontracting plan requirements.

(a)(1) The goal for use of small disadvantaged business concerns shall include subcontracts with historically black colleges and universities and minority institutions (see subpart 226.70), in addition to subcontracts with small disadvantaged business concerns. Subcontracts with historically black colleges and universities and minority institutions do not have to be included in the small disadvantaged business goal in plant, division, or company-wide commercial products subcontracting plans.

219.705 Responsibilities of the contracting officer under the subcontracting assistance program.

219.705–2 Determining the need for a subcontracting plan.

(d) The extent to which offerors identify and commit to small disadvantaged business, historically black college and university, or minority institution performance of the contract, whether as joint venture, teaming arrangement, or subcontractor, shall be an evaluation factor in source selection for major systems acquisitions and other complex or sensitive acquisitions which use formal or alternative source selection procedures.

219.705–4 Reviewing the subcontracting plan.

(d) Challenge any subcontracting plan that does not contain positive goals and consider the extent to which an offeror plans to use competition restricted to small disadvantaged business concerns, historically black colleges and universities, or minority institutions. A small disadvantaged business goal of less than five percent must be approved two levels above the contracting officer.

219.706 Responsibilities of the cognizant administrative contracting officer.

(a)(i) The contract administration office also is responsible for reviewing, evaluating, and approving master subcontracting plans.

(ii) The small and disadvantaged business utilization specialist supports the administrative contracting officer in evaluating a contractor's performance and compliance with its subcontracting plan.

219.708 Solicitation provisions and contract clauses.

(b) Use the clause at 252.219–7000, Small Business and Small Disadvantaged Business Subcontracting Plan (DoD Contracts), in solicitations and contracts that contain the clause at FAR 52.219–9, Small Business and Small Disadvantaged Business Subcontracting Plan.

(1) In contracts with contractors which have comprehensive subcontracting plans approved under the test program described in 219.702(a), use the clause at 252.219–7006, Small Business and Small Disadvantaged Business Subcontracting Plan (Test Program), instead of the clauses at 252.219–7000, Small Business and Small Disadvantaged Business Subcontracting Plan (DoD Contracts), and FAR 52.219–9, Small Business and Small Disadvantaged Business Subcontracting Plan.

(2) In contracts with contractors which have comprehensive subcontracting plans approved under the test program described in 219.702(a), use the clause at 252.219–7007, Liquidated Damages—Small Business Subcontracting Plan (Test Program), instead of the clause at FAR 52.219–16, Liquidated Damages—Small Business Subcontracting Plan.

(c)(1) Do not use the clause at FAR 52.219–10, Incentive Subcontracting Program for Small and Small Disadvantaged Business Concerns.

(A) When contracting by negotiation, use the clause at 252.219–7005, Incentive for Subcontracting With Small Businesses, Small Disadvantaged Businesses, Historically Black Colleges and Universities, and Minority Institutions, in all solicitations and contracts that contain the clause at FAR 52.219–9, Small Business and Small Disadvantaged Business Subcontracting Plan.

(B) Use the clause at 252.219–7005 with its Alternate I when, in the judgment of the contracting officer, inclusion of an incentive is necessary to increase subcontracting opportunities for other small businesses.

(C) Determine the percentage to be negotiated and used in the clause by considering the type and extent of effort required to exceed the goal, for example—

(*1*) Unique outreach programs;

(*2*) Use of small disadvantaged businesses, historically black colleges and universities, and minority institutions in nontraditional areas;

(*3*) Technical assistance to qualify or assist these entities; and

(*4*) Proximity of subcontractors to the prime.

(D) Do not use the clause at 252.219–7005 and FAR 52.219–10 in contracts with contractors which have comprehensive subcontracting plans approved under the test program described in 219.702(a).

(2) For negotiated acquisitions of $10 million or more, the contracting officer may use an award fee provision instead of the incentive provision required by (c)(1)(A) of this section. When an award fee provision is used, do not use the clauses at 252.219–7005, Incentive for Subcontracting With Small Businesses, Small Disadvantaged Businesses, Historically Black Colleges and Universities, and Minority Institutions, and FAR 52.219–10, Incentive Subcontracting Program for Small and Small Disadvantaged Business Concerns. Do not use award fee provisions in contracts with contractors which have comprehensive subcontracting plans approved under the test program described in 219.702(a).

Subpart 219.8—Contracting With the Small Business Administration (the 8(a) Program)

219.803 Selecting acquisitions for the 8(a) Program.

(c) Before considering the set-aside order of precedence in 219.504(b), review the acquisition for offering under the 8(a) Program.

219.804 Evaluation, offering, and acceptance.

219.804–1 Agency evaluation.

When SBA asks for a requirement for the 8(a) Program, offer the requirement if appropriate, and do not use the small disadvantaged business set-aside procedure. If an acquisition, other than a repetitive acquisition (as described in FAR 19.804–4), was synopsized using either of the notices in 205.207(d) (72) or (73) before receipt of the SBA request, the request does not have to be honored.

(f) The 8(a) firms should be offered the opportunity to give a technical presentation.

Subpart 219.10—Small Business Competitiveness Demonstration Program

219.1005 Applicability.

(a) (S–70) Dredging (SIC 1629, FPDS V216–Z216). This applies to the Army Corps of Engineers.

(b) The targeted industry categories for DoD are:

Standard Industrial Classification (SIC)	SIC Code
(1) Pharmaceutical preparations	2834
(2) Ammunition, except for small arms	3483
(3) Ordnance and accessories, not elsewhere classified	3489
(4) Turbines and turbine generator sets	3511
(5) Aircraft engines and engine parts	3724
(6) Guided missiles and space vehicles	3761
(7) Space vehicle equipment, NEC	3769
(8) Tanks and tank components	3795
(9) Search and navigation equipment	3812
(10) Communication services, NEC	4899

219.1006 Procedures.

(b)(1) During the period when small business set-asides cannot be considered for acquisitions in the four designated industry groups—

(A) The 219.502–2(a) requirements for setting aside acquisitions are waived;

(B) The restrictions at 219.502–270(b) (1), (2), and (3) do not apply and the acquisitions shall be considered for small disadvantaged business set-asides; and

(C) The evaluation preference at subpart 219.70 shall not be used.

(2) The Office of the Secretary of Defense (OSD) will decide whether to reinstate small business set-asides and will advise the departments and defense agencies. Military departments and defense agencies shall not reinstate small business set-asides unless directed by the OSD.

219.1006–70 Reporting procedures.

Reporting requirements are at 204.675.

219.1007 Solicitation provisions and contract clauses.

Do not use the clause at 252.219–7002, Notice of Evaluation Preference for Small Disadvantaged Business Concerns, in solicitations or contracts for the four designated industry groups.

Subpart 219.70—Evaluation Preference for Small Disadvantaged Business (SDB) Concerns

219.7000 Policy.

Offers from small disadvantaged business concerns shall be given an evaluation preference in accordance with this subpart.

219.7001 Applicability.

(a) The evaluation preference shall be used in competitive acquisitions where award is based on price and price related factors. The preference may be used at the discretion of the source selection authority in other competitive acquisitions.

(b) Do not use the evaluation preference in acquisitions which—

(1) Use small purchase procedures;

(2) Are set-aside for small disadvantaged businesses;

(3) Are set-aside for small businesses; or

(4) Are for commissary or exchange resale.

219.7002 Procedures.

(a) Give offers from small disadvantaged business concerns a preference in evaluation by adding a factor of ten percent to the price of all offers, except—

(1) Offers from small disadvantaged business concerns;

(2) Offers from historically black colleges and universities or minority institutions;

(3) Offers of—

(i) Eligible products under the Trade Agreements Act when the acquisition equals or exceeds the dollar threshold in FAR 25.402; or

(ii) Qualifying country end products (see the definition in 225.101); and

(4) Offers where application of the factor would be inconsistent with a Memorandum of Understanding or other

international agreement with a foreign government.

(b) Apply the factor on a line item by line item basis or apply it to any group of items on which award may be made. Add other evaluation factors such as transportation costs or rent-free use of Government facilities to the offers before applying the ten percent factor.

(c) Do not evaluate offers using the preference when it would cause award to be made at a price which exceeds fair market price by more than ten percent.

219.7003 Solicitation provisions and contract clauses.

Use the clause at 252.219-7003, Notice of Evaluation Preference for Small Disadvantaged Business Concerns, in solicitations and contracts involving the evaluation preference. Use the clause with its Alternate I when the contracting officer determines that there are no small disadvantaged business manufacturers that can meet the requirements of the solicitation.

PART 220—[Removed]

5. Part 220 is removed in its entirety.

6. Part 224 is revised to read as follows:

PART 224—PROTECTION OF PRIVACY AND FREEDOM OF INFORMATION

Subpart 224.1—Protection of Individual Privacy

Sec.
224.102 General.
224.103 Procedures.

Subpart 224.2—Freedom of Information Act

224.202 Policy.

Authority: 5 U.S.C. 301,10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

Subpart 224.1—Protection of Individual Privacy

224.102 General.

The Act does not apply to:

(1) Systems of records the contractor maintains on its employees; or

(2) The records generated by a state or private educational organization under a contract with the Government to provide training, when the records (admission forms, grade reports) are similar to and commingled with those maintained on other students.

224.103 Procedures.

(b)(2) DoD rules and regulations are contained in DoD Directive 5400.11, Department of Defense Privacy Program.

Subpart 224.2—Freedom of Information Act

224.202 Policy.

(a) DoD implementation is in DoD Directive 5400.7, DoD Freedom of Information Act Program, and DoD Regulation 5400.7-R, DoD Freedom of Information Act Program.

7. Part 226 is revised to read as follows:

PART 226—OTHER SOCIOECONOMIC PROGRAMS

Subpart 226.70—Historically Black Colleges and Universities and Minority Institutions

Sec.
226.7000 Scope of subpart.
226.7001 Definitions.
226.7002 General Policy.
226.7003 Set-asides for HBCUs and MIs.
226.7003-1 Set-aside criteria.
226.7003-2 Set-aside procedures.
226.7004 Evaluation preference for HBCUs and MIs.
226.7005 Eligibility as an HBCU or MI.
226.7006 Protesting an HBCU or MI representation.
226.7007 Goals and incentives for subcontracting with HBCU/MIs.
226.7008 Solicitation provision and contract clause.

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

Subpart 226.70—Historically Black Colleges and Universities and Minority Institutions

226.7000 Scope of subpart.

This subpart implements the historically black college and university (HBCU) and minority institution (MI) aspects of section 1207 of Public Law 99-661, section 806 of Public Law 100-180, and section 831 of Public Law 101-189. These laws set a goal for DoD for each of fiscal years 1987-1993 to—

(a) Award five percent of contract and subcontract dollars to small disadvantaged business concerns and HBCU/MIs; and

(b) Maximize the number of such entities in DoD contracting and subcontracting.

226.7001 Definitions.

Definitions of HBCUs and MIs are in the clause at 252.226-7000.

226.7002 General Policy.

The DoD will use outreach efforts, technical assistance programs, advance payments, HBCU/MI set-asides, and evaluation preferences to meet its contract and subcontract goal for use of HBCUs and MIs.

226.7003 Set-asides for HBCUs and MIs.

226.7003-1 Set-aside criteria.

Set-aside acquisitions for exclusive HBCU and MI participation when the acquisition is for research, studies, or services of the type normally acquired from higher educational institutions and there is a reasonable expectation that—

(a) Offers will be submitted by at least two responsible HBCUs or MIs which can comply with the subcontracting limitations in the clause at FAR 52.219-14;

(b) Award will be made at not more than ten percent above fair market price; and

(c) Scientific and/or technological talent consistent with the demands of the acquisition will be offered.

226.7003-2 Set-aside procedures.

(a) As a general rule, use competitive negotiation for HBCU/MI set-asides.

(b) When using a broad agency announcement (FAR 35.016) for basic or applied research, make partial set-asides for HBCU/MIs as explained in 235.016(a)(S-70).

(c) Follow the special synopsis instructions in 205.207(d) (S-74), (S-75), and (S-76).

(d) Cancel the set-aside if the low responsible offer exceeds the fair market price (defined in FAR part 19) by more than ten percent.

226.7004 Evaluation preference for HBCUs and MIs.

In acquisitions which use the evaluation preference described in subpart 219.70 for small disadvantaged business concerns, the preference also applies to offers from HBCUs or MIs.

226.7005 Eligibility as an HBCU or MI.

(a) To be eligible for award as an HBCU or MI under the preference procedures of this subpart, an offeror must—

(1) Be an HBCU or MI, as defined in the clause at 252.226-7000, both at the time of submission of its offer and at contract award; and

(2) Provide the contracting officer with evidence of its HBCU or MI status upon request.

A list of HBCUs is published periodically by the Department of Education.

(b) The contracting officer shall accept an offeror's certification under the provision at 252.226-7001 that it is an HBCU or MI, unless—

(1) Another offeror challenges the certification; or

(2) The contracting officer has reason to question the offeror's HBCU/MI status.

226.7006 Protesting an HBCU or MI representation.

Any offeror or other interested party may challenge an offeror's HBCU or MI representation by filing a protest with the contracting officer. The protest must contain specific detailed evidence supporting the basis for the challenge. Such protests are handled in accordance with FAR 33.103 and are decided by the contracting officer.

226.7007 Goals and incentives for subcontracting with HBCU/MIs.

(a) In reviewing subcontracting plans submitted under the clause at FAR 52.219–9, Small Business and Small Disadvantaged Business Subcontracting Plan, the contracting officer shall—

(1) Ensure that the contractor included anticipated awards to HBCU/MIs in the small disadvantaged business goal;

(2) Consider whether subcontracts are contemplated which involve research or studies of the type normally performed by higher educational institutions.

(b) Use of incentives for subcontracting with HBCU/MIs is prescribed in 219.708(c)(1).

226.7008 Solicitation provision and contract clause.

(a) Use the clause at 252.226–7000, Notice of Historically Black College or University and Minority Institution Set-Aside, in solicitations and contracts set-aside for HBCU/MIs.

(b) Use the provision at 252.226–7001, Historically Black College or University and Minority Institution Certification, in solicitations set-aside for HBCU/MIs and in solicitations which contain the clause at 252.219–7003, Notice of Evaluation Preference for Small Disadvantaged Business Concerns.

8. Part 229 is revised to read as follows:

PART 229—TAXES

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

Subpart 229.1—General

229.101 Resolving tax problems.

(a) Within DoD, the agency-designated legal counsels are:

Army—Chief, Contract Law Division, Office of the Judge Advocate General
Navy—General Counsel
Air Force—General Counsel
Defense Logistics Agency—General Counsel
National Security Agency—General Counsel
Defense Communications Agency—General Counsel
Defense Nuclear Agency—General Counsel
Defense Mapping Agency—General Counsel

(c) The contracting officer may direct the contractor to litigate the applicability of a particular tax if—

(i) The contract is either a cost reimbursement type or a fixed price type with a tax escalation clause, and

(ii) The direction is coordinated with the agency-designated legal counsel through the DoD Tax Policy and Advisory Group.

(d)(i) Review DoD Directive 5100.64, Department of Defense Foreign Tax Relief Program, before contracting with a foreign source. Refer questions on implementation of the program to the following Commanding Officers, which have been designated under subsection E.7 of DoDD 5100.64 to serve as—

(A) Single point of contact for U.S. contracting offices for investigation and resolution of specific foreign tax relief matters, and

(B) Liaison with responsible diplomatic mission and local foreign tax authorities:

Country or area	Designated commanding officer
Australia	Commander in Chief, Pacific Representative, Australia.
Azores	Commander, U.S. Forces, Azores.
Bahrain	Commander in Chief, U.S. Naval Forces, Europe.
Belgium	Commander in Chief, U.S. Army, Europe.
Bermuda	Commanding Officer, U.S. Naval Air Station, Bermuda.
Canada	Commander, Space Command.
Caribbean Islands (including Bahamas).	Commander, Antilles Defense Command.
Denmark	Commander in Chief, U.S. Air Forces, Europe.
Ethiopia	Commander in Chief, U.S. Army, Europe.
France	Commander in Chief, U.S. Army, Europe.
Germany	Commander in Chief, U.S. Army, Europe.
Greece	Commander in Chief, U.S. Air Forces, Europe.
Greenland	Commander, Space Command.
Iceland	Commander, Iceland Defense Force.
Iran	Commander in Chief, U.S. Army, Europe.
Italy	Commander in Chief, U.S. Naval Forces, Europe.
Japan	Commander, U.S. Forces, Japan.
Korea	Commander, U.S. Forces, Korea.
Luxembourg	Commander in Chief, U.S. Army, Europe.
Morocco	Commander in Chief, U.S. Naval Forces, Europe.
Netherlands	Commander in Chief, U.S. Air Forces, Europe.
New Zealand	Commander, U.S. Naval Support Forces, Antarctica.
Norway	Commander in Chief, U.S. Air Forces, Europe.
Philippines	Commander in Chief, Pacific Representative, Philippines.
Portugal	Commander in Chief, U.S. Naval Forces, Europe.
Spain	Commander in Chief, U.S. Air Forces, Europe.
Taiwan	Commander, U.S. Military Assistance Command, Thailand.
Turkey	Commander in Chief, U.S. Air Forces, Europe.
United Kingdom	Commander in Chief, U.S. Air Forces, Europe.

Refer foreign tax relief questions which have not been resolved by the designated Commanding Officer to the agency-designated legal counsel.

(ii) When an acquisition is for a contract to be performed in a country or area listed in paragraph (d)(i)(B) of this section—

(A) Obtain from the designated Commanding Officer detailed information concerning the taxes and duties from which the Government of the United States is exempt, and

(B) Provide the information to prospective offerors.

(C) Do not provide prospective offerors any other information about foreign taxes or duties.

(D) Issue tax exemption certificates, as appropriate, to assist the contractor in obtaining relief from foreign taxes and duties which were excluded from the contract price.

(E) Seek advice and assistance from the designated Commanding Officer and, if necessary, the agency-designated legal counsel if the contractor notifies the contracting officer that it has been assessed a tax or duty by a foreign government which could increase the contract price.

9. Part 231 is revised to read as follows:

PART 231—CONTRACT COST PRINCIPLES AND PROCEDURES

Subpart 231.2—Contracts With Commercial Organizations

Sec.
231.205 Selected costs.
231.205–1 Public relations and advertising costs.
231.205–10 Cost of money.
231.205–18 Independent research and development and bid and proposal costs.
231.205–38 Selling costs.
231.270 Solicitation provisions and contract clauses.

Subpart 231.70—Penalties for Unallowable Costs

231.7000 Scope of Subpart.
231.7001 General.
231.7002 Responsibilities.
231.7003 Procedures.

231.7003–1 Assessing the penalty.
231.7003–2 Computing the penalty.
231.7004 Contract clause.

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

Subpart 231.2—Contracts with Commercial Organizations

231.205 Selected costs.

231.205–1 Public relations and advertising costs.

(f)(2) These costs are allowable if incurred as part of a significant effort to promote export sales of U.S. defense industry products.

(8) The costs made allowable under 231.205–38(c) are also an exception.

(g) This does not apply to the DoD.

231.205–10 Cost of money.

The contractor also must comply with Subpart 230.70 and maintain records to demonstrate compliance.

231.205–18 Independent research and development and bid and proposal costs.

(c) The total amount of IR&D/B&P costs allocated to DoD contracts shall not exceed the total of expenditures for IR&D/B&P projects with a potential military relationship.

(i) For contracts where costs are not determined on a historical basis, estimated IR&D/B&P costs allocated to the contract must not exceed their proportionate share of the total estimated costs of IR&D/B&P with a potential military relationship.

(ii) IR&D/B&P costs are considered to satisfy the potential military relationship requirement when the contractor can demonstrate that the effort under a proposed contract or grant would have a potential relationship to a military function or operation.

(iii) The contracting officer will—

(A) Determine the potential military relationship of IR&D/B&P; and

(B) Provide the results of the determination to the contractor.

(iv) See 225.7304 for additional allowability provisions affecting foreign military sale contracts.

231.205–38 Selling costs.

(b) Other market planning costs are allowable to the extent that they are reasonable and comply with the provisions of paragraph (c) of this subsection.

(c) The costs of broadly-targeted and direct selling efforts and market planning other than long range, which are incurred in connection with a significant effort to promote export sales of products of the U.S. defense industry, including the costs of exhibiting and demonstrating such products, are allowable on contracts with the DoD provided:

(i) The costs are allocable, reasonable, and otherwise allowable under this subpart and FAR part 31. Costs normally unallowable under FAR 31.205–1(f)(2)(i) and (iii), (f)(5), and (f)(8) are allowable if they meet the requirements of 231.205–38(c).

(ii) That, for a business segment which allocates to DoD contracts $2,500,000 or more of such costs in any fiscal year of such business segment, the allowable amount shall not be in excess of 110 percent of such costs incurred by the business segment in the previous fiscal year.

(iii) In order to comply with Public Law 100–456, the substance of this paragraph (c) shall apply to all DoD contracts and subcontracts of the contractor, which are being performed by the contractor on the first day of the contractor's first full fiscal year that begins on or after December 22, 1988, whether or not a contract or subcontract contains this paragraph (c). This paragraph (c)(iii) is effective until September 30, 1991.

(d) The cost of selling efforts other than those addressed in FAR 31.205–38 (b) or (c) or paragraph (c) of this subsection are unallowable.

(f) Additional allowability provisions for foreign military sale contracts are in 225.7304 and 225.7305.

231.270 Solicitation provisions and contract clauses.

Use the clause at 252.231–7000, Supplemental Cost Principles, in all solicitations and contracts, except those which use the small purchase procedures of FAR part 13.

Subpart 231.70—Penalties for Unallowable Costs

231.7000 Scope of Subpart.

(a) This subpart implements 10 U.S.C. 2324(a) through (d), which requires that the DoD assess penalties against contractors which include unallowable costs in a final indirect cost rate proposal or any other proposal that includes incurred and accrued indirect costs.

(b) This subpart applies to all DoD contracts awarded after February 26, 1987, in excess of $100,000, except firm fixed-price contracts.

231.7001 General.

(a) The law provides for the following penalties:

(1) If the cost is unallowable based on clear and convincing evidence, the penalty is equal to—

(i) The amount of the disallowed costs, plus

(ii) Interest on the paid portion, if any, of the disallowance.

(2) If the cost was determined to be unallowable before proposal submission, the penalty is the amount in paragraph (a)(1) of this section plus two times the amount of the disallowed cost.

(3) If a penalty is assessed under paragraphs (a) (1) or (2) of this section, the agency may assess an additional penalty of not more than $10,000 per proposal.

(b) These penalties are in addition to other civil and criminal penalties provided by law.

(c) It is not necessary for unallowable costs to have been paid to the contractor in order to assess a penalty.

231.7002 Responsibilities.

(a) Agencies are responsible for—

(1) Designating officials authorized to assess the penalty in 231.7001(a)(3).

(2) Establishing requirements for documentation and review of administrative contracting officer (ACO) determinations and recommendations to assess the penalties in 231.7001(a).

(b) The cognizant ACO is responsible for—

(1) Determining whether the penalties in 231.7001(a) (1) and (2) should be assessed.

(2) Initiating recommendations to assess the penalty under 231.7001(a)(3).

(3) If there is evidence that the contractor knowingly submitted unallowable costs—

(i) Referring the matter to the appropriate Defense criminal investigative organization for review; and

(ii) Taking the actions indicated in DoDD 7050.5, Coordination of Remedies for Fraud and Corruption Relating to Procurement Activities.

(c) The contract auditor, in review and/or determination of final rate proposals for contracts subject to this Subpart, is responsible for—

(1) Recommending to the ACO which costs may be unallowable and subject to the penalties in 231.7001(a) (1) and (2).

(2) Providing rationale and supporting documentation for any recommendation.

231.7003 Procedures.

231.7003–1 Assessing the penalty.

(a) The cognizant ACO shall—

(1) Assess the penalty in 231.7001(a)(1) when the submitted cost is unallowable based on clear and convincing evidence; or

(2) Assess the penalty in 231.7001(a)(2) when the submitted cost was determined to be unallowable prior to submission of the proposal. Prior

determinations of unallowability may be evidenced by—

(i) A DCAA Form 1, Notice of Contract Costs Suspended and/or Disapproved, (see FAR 42.705–2) which—

(A) The contractor elected not to appeal; or

(B) Was not withdrawn by DCAA.

(ii) A contracting officer final decision which was not appealed.

(iii) Prior ASBCA or court decision involving the contractor, which upheld the cost disallowance.

(iv) Any determination of unallowability under FAR 31.201–6.

(3) Issue a final decision (see FAR 33.211) which includes a demand for payment of any penalty assessed under 231.7001(a) (1) or (2). The letter shall state that the determination is a final decision under the Disputes clause of the contract. (Demanding payment of the penalty is separate from demanding repayment of any paid portion of the disallowed cost.)

(b) The designated agency official, after receiving the ACO's recommendation and where circumstances warrant the additional penalty, may assess the penalty in 231.7001(a)(3). Appropriate circumstances may include contractor's repeated submissions of unallowable costs.

231.7003–2 Computing the penalty.

(a) The amount of the disallowed costs subject to penalty is the amount submitted in the contractors proposal which—

(1) Is allocated to contracts subject to this subpart (see 231.7000(b)); and

(2) Is determined to be unallowable based on clear and convincing evidence.

(b) Compute interest on the paid portion of the disallowed cost.

(1) Consider the overpayment to have occurred, and interest to have started running, from the midpoint of the contractor's fiscal year. Use an alternate equitable method if the cost was not incurred and paid evenly over the fiscal year.

(2) Use the interest rate specified by the Secretary of Treasury pursuant to Public Law 92–41.

(3) Compute interest from the date of overpayment to the date of the demand letter for payment of the penalty.

(4) Determine the paid portion of the disallowed cost in consultation with the contract auditor.

231.7004 Contract clause.

Use the clause at 252.231–7001, Penalties for Unallowable Costs, in all solicitations and contracts over $100,000, except firm fixed-price contracts.

10. Part 233 is revised to read as follows:

PART 233—PROTESTS, DISPUTES, AND APPEALS

Subpart 233.2—Disputes and Appeals

Sec.

Subpart 233.70—Certification of Claims and Requests for Adjustment or Relief

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

Subpart 233.2—Disputes and Appeals

233.204 Policy.

Before settling a current claim, the contracting officer, when appropriate, should get information on claims previously filed with other contracting officers.

233.210 Contracting officer's authority.

10 U.S.C. 2405 prohibits adjustments in price under a shipbuilding contract entered into after December 7, 1983, for a claim, request for equitable adjustment, or demand for payment, arising out of events occurring more than 18 months before submission of the claim, request, or demand.

233.214 Contract clause.

Use Alternate I of the clause at FAR 52.233–1, Disputes, when—

(1) The acquisition is for—

(i) Aircraft

(ii) Spacecraft and launch vehicles

(iii) Naval vessels

(iv) Missile systems

(v) Tracked combat vehicles

(vi) Related electronic systems;

(2) The contracting officer determines that continued performance is—

(i) Vital to the national security, or

(ii) Vital to the public health and welfare; or

(3) The head of the contracting activity determines that continued performance is necessary pending resolution of any claim arising under or relating to the contract.

Subpart 233.70—Certification of Claims and Requests for Adjustment or Relief

233.7000 Policy.

(a) Contractors must make a good faith certification for a claim or request over $100,000 at the time of submission of a claim (see definition in FAR 33.201), request for equitable adjustment, or request for relief under Public Law 85–804 (see FAR part 50), or other similar request. The certification must be signed by a senior company official in charge at the contractor's plant or location involved.

(b) Submission of the certification in paragraph (a) of this section is in addition to any certification required by FAR part 15 or FAR part 33, except the certification requirement in FAR 33.207 will satisfy the requirement in 233.7000(a) for certification of a claim if the certification is signed by a senior company official.

233.7001 Contract clause.

Use the clause at 252.233–7000, Certification of Claims and Requests for Adjustment or Relief, in all contracts expected to exceed $100,000.

11. Part 243 is revised to read as follows:

PART 243—CONTRACT MODIFICATIONS

Subpart 243.1—General

Sec.

Subpart 243.2—Change Orders

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

Subpart 243.1—General

243.102 Policy.

(b)(i) See 217.7503 for limitations on issuing unpriced contract modifications.

(ii) Modifications of letter contracts are subject to the same policies and procedures as modifications of definitive contracts.

243.107 Contract clause.

For DoD, the "specifically authorized representative" (SAR) referred to in the clause at FAR 52.243–7, Notification of Changes, is a "contracting officer's representative" as defined in 202.101.

243.107–70 Identification of foreign military sale (FMS) requirements.

Identify contract modifications that add FMS requirements by clearly marking "FMS Requirement" on the front. Within the modification, cite each FMS case identifier code by line/subline item number, e.g., FMS Case Identifier GY–D–DCA.

Subpart 243.2—Change Orders

243.205 Contract clauses.

243.205-70 Engineering change proposals.

Engineering changes can originate with either the contractor or the Government. In either case, the Government will need detailed information from the contractor for evaluation of the technical, cost, and schedule effects of implementing the change. When the contracting officer wants this information submitted in the format prescribed by MIL-STD-480, use the clause at 252.243-7000, Engineering Change Proposals. Use the clause with its Alternate I, when appropriate, to discourage submission of a large number of small dollar, contractor originated engineering change proposals.

243.205-71 Pricing of contract modifications.

Use the clause at 252.243-7001, Pricing of Contract Modifications, in solicitations and contracts when anticipating and using a fixed price type contract.

12. Part 248 is revised to read as follows:

PART 248—VALUE ENGINEERING

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

Subpart 248.2—Contract Clauses

248.270 Supplemental clause.

When one of the clauses prescribed by FAR subpart 48.2 is used and the contracting officer wants value engineering change proposals submitted in the format prescribed by MIL-STD-480 or 481, use the clause at 252.248-7000, Preparation of Value Engineering Change Proposals.

13. Part 250 is revised to read as follows:

PART 250—EXTRAORDINARY CONTRACTUAL ACTIONS

Sec.

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

250.001 Definitions.

As used in this part,

Agency head does not include heads of defense agencies.

Secretarial level means—

(1) An official at or above the level of an Assistant Secretary (or Deputy) of Defense or of the Army, Navy, or Air Force, and

(2) A contract adjustment board established by the Secretary concerned.

Subpart 250.1—General

250.103 Deviations.

For deviation purposes, "defense agencies" include the Departments of the Army, Navy, and Air Force, as well as agencies under the purview of the Office of the Secretary of Defense.

250.104 Reports.

Departmental and agency supplements identify officials responsible for preparing and processing the reports required by this section.

250.105 Records.

(1) Departments and agencies will—

(i) Prepare a preliminary record when a request for a contract adjustment under FAR subpart 50.3 is filed (see 250.305-70).

(ii) Prepare a final record stating the disposition of the request (see 250.306-70).

(iii) Designate the offices or officials responsible for preparing and submitting all records required by this part 250. Records shall be maintained by the Contract Adjustment Boards of the Army, Navy, and Air Force, respectively, and by the headquarters of the defense agencies.

(2) A suggested format for the records follows. This format permits the information required for the preliminary and final records to be combined on one form.

BILLING CODE 3810-01-M

☐ PRELIMINARY	RECORD OF REQUEST FOR ADJUSTMENT PUBLIC LAW 85-804	FINAL ☐
DATE OF REQUEST		DATE RECEIVED BY GOVERNMENT
CONTRACTOR'S NAME AND ADDRESS ☐ SMALL BUSINESS		
NAME AND ADDRESS OF CONTRACTOR'S REPRESENTATIVE, IF ANY		
COGNIZANT CONTRACTING OFFICER OR OFFICE		CONTRACTING ACTIVITY
PROPERTY OR SERVICE INVOLVED		EXTENT OF PERFORMANCE AS OF DATE OF REQUEST
CONTRACT NUMBER	DATE	SEALED BID OR NEGOTIATED / TYPE OF CONTRACT
CATEGORY OF CASE		AMOUNT OR DESCRIPTION OF REQUEST
ACTION BELOW SECRETARIAL LEVEL		DATE
ACTION BY CAB		DATE
IMPLEMENTATION		DATE
ADDITIONAL DATA OR REMARKS		
DATE THIS RECORD SIGNED	SIGNATURE	

BILLING CODE 3810-01-M

(3) The following instructions are provided for those items which are not self-explanatory:

(i) *Extent of performance as of date of request.* State degree of completion of contract; e.g., 50 percent completed or performance not yet begun. If work is completed, state date of completion and whether final payment has been made.

(ii) *Award procedure.* State whether contract was awarded under sealed bidding or negotiated procedures. Cite specific authority for using other than full and open competition, if applicable, e.g., 10 U.S.C. 2304(c)(1).

(iii) *Type of contract.* State type of contract (see FAR part 16); e.g., FFP (firm fixed-price).

(iv) *Category of case.* State whether the request involves an amendment without consideration, a mistake, or an informal commitment. If the case involves more than one category, identify both; list the most significant category first.

(v) *Amount or description of request.* If the request is expressed in dollars, state the amount and whether it is an increase or decrease. If the request cannot be expressed in monetary terms, provide a brief description; e.g., "Cancellation" or "Modification." Even if the adjustment is not easily expressed in terms of dollars, if the contractor has made an estimate in the request, that estimate should be stated.

(vi) *Action below Secretarial level.* State the disposition of the case, the office that took the action and the date the action was taken. The disposition should be stated as "Withdrawn," "Denied," "Approved," or 'Forwarded." If the request was approved, in whole or in part, state the dollar amount or nature of the action (as explained in paragraph (3)(v) of this section. The date should correspond with the date of the memorandum of decision or of the letter forwarding the request to the contract adjustment board or other deciding body.

(vii) *Action by contract adjustment board and date.* State the disposition and date of disposition of the case by the contract adjustment board. Provide the same information as for paragraph (3)(vi) of this section.

(viii) *Implementation and date.* State the appropriate action; e.g., "Amendment," "New Contract," or "Letter of Denial."

Subpart 250.2—Delegation of and Limitations on Exercise of Authority

250.201 Delegation of authority.

(b) Authority under FAR subpart 50.4 to approve actions obligating $50,000 or less may not be delegated below the level of the head of the contracting activity; however, see FAR 50.201(d) for indemnification authority.

250.201-70 Delegations.

(a) *Military Departments.* The Departments of the Army, Navy and Air Force will specify delegations and levels of authority for actions under the Act and the Executive Order in departmental supplements.

(b) *Defense Agencies.* Subject to the restrictions on delegations of authority in 250.201(b) and FAR 50.201, the Directors of the Defense Logistics Agency, the Defense Nuclear Agency, the National Security Agency, and the Defense Mapping Agency may exercise and redelegate the authority contained in the Act and the Executive Order. The agency supplements shall specify the delegations and levels of authority. Actions in excess of the authority delegated by this subsection must be submitted to the Assistant Secretary of Defense, Production and Logistics, for approval.

(c) *Approvals.* The service Secretary or agency Director must approve any delegations in writing.

250.202 Contract adjustment boards.

The Departments of the Army, Navy, and Air Force each have a contract adjustment board. The board consists of a Chair and not less than two nor more than six other members, one of whom may be designated the Vice-Chair. A majority constitutes a quorum for any purpose and the concurring vote of a majority of the total board membership constitutes an action of the board. Alternates may be appointed to act in the absence of any member.

Subpart 250.3—Contract Adjustments

250.303 Contractor requests.

Requests should be filed with the procuring contracting officer (PCO). If a request is filed with an administrative contracting officer (ACO), the ACO shall promptly forward it to the PCO for appropriate action. If filing with the PCO is impracticable, requests may be filed with the following addresses for forwarding to the cognizant PCO:

(1) Army or Navy: The head of the contracting activity listed in part 202 which appears to be cognizant of the contract or commitment involved.

(2) Air Force: Commander, Air Force Logistics Command, ATTN: PPC, Wright-Patterson Air Force Base, Ohio.

(3) Defense Logistics Agency: The Commander of the Defense Supply Center involved.

(4) Defense Communications Agency: Director, DCA, ATTN: Code 260.

(5) Defense Nuclear Agency: Director, DNA, ATTN: OAPR.

(6) National Security Agency: Director, NSA.

(7) Defense Mapping Agency: Director, DMA, ATTN: LO.

250.305 Processing cases.

250.305-70 Record of request.

At the time the request is filed, the activity will prepare the record described at 250.105(1)(i) and forward it to the appropriate official within 30 days after the close of the month in which the record is prepared.

250.305-71 Processing cases to contract adjustment boards.

(a) The officer or official responsible for the case shall forward the contract adjustment board two copies of the following:

(1) A letter stating—

(i) The nature of the case;

(ii) The basis for the board's authority to act;

(iii) The findings of fact essential to the case (see FAR 50.304). Arrange the findings chronologically with cross references to supporting enclosures;

(iv) The conclusions drawn;

(v) The recommended disposition; and

(vi) If contractual action is recommended, a statement by the signer that the action will facilitate the national defense.

(2) The contractor's request

(3) All evidentiary materials

(4) All endorsements, reports and comments of cognizant Government officials

(b) A letter to the Board recommending an amendment without consideration (see FAR 50.302-1(a)) should—

(1) Provide the information required by FAR 50.304 (a) and (b), and

(2) Findings as to—

(i) The contractor's performance record, including the quality of product, rate of production, and promptness of deliveries;

(ii) The importance to the Government, particularly to the active duty military, of the performance of the contract and the importance of the contractor to the national defense;

(iii) The forecast of future contracts with the contractor; and

(iv) Other available sources of supply for the supplies or services covered by the contract, and the time and cost of having contract performance completed by such other sources.

250.305-72 Processing by the board.

Contract adjustment boards will render decisions as expeditiously as

practicable. The Chair shall sign a memorandum of decision disposing of the case. The decision shall be dated and shall contain the information required by FAR 50.306. The memorandum of decision shall not contain any information classified "Confidential" or higher. The board's decision will be sent to the appropriate official for implementation.

250.306 Disposition.

250.306-70 Record of disposition.

(a) When the request for relief is denied or approved below the Secretarial level, submit the following documents to the appropriate office within 30 days after the close of the month in which the decision is executed:

(1) Two copies of the memorandum of decision;

(2) Except for the Army, one copy of the contractual document implementing any decision approving contractual action; and

(3) One copy of a final record, as described at 250.105.

(b) When a contract adjustment board decision is implemented, the activity which forwarded the case to the board shall prepare and submit to the board the documents identified in paragraphs (a) (2) and (3).

Subpart 250.4—Residual Powers

250.403 Special procedures for unusually hazardous or nuclear risks.

250.403-70 Indemnification under contracts involving both research and development and other work.

When indemnification is to be provided on contracts requiring both research and development work and other work, the contracting officer shall insert an appropriate clause using the authority of both 10 U.S.C. 2354 and Public Law 85-804.

(a) The use of Public Law 85-804 is limited to work which cannot be indemnified under 10 U.S.C. 2354 and is subject to compliance with FAR subpart 50.4

(b) Indemnification under 10 U.S.C. 2354 is covered by 235.070.

14. Part 251 is revised to read as follows:

PART 251—USE OF GOVERNMENT SOURCES BY CONTRACTORS

Subpart 251.1—Contractor Use of Government Supply Sources

Sec.

Subpart 251.2—Contractor Use of Interagency Fleet Management System (IFMS) Vehicles

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

Subpart 251.1—Contractor Use of Government Supply Sources

251.100 Scope of subpart.

FAR subpart 51.1 and this subpart apply to the acquisition of supplies to be delivered in the United States, its possessions, or Puerto Rico. (Grantees cannot be authorized to use General Services Administration (GSA) sources.)

251.102 Authorization to use Government supply sources.

(e) Use the following format:

Subject: Authorization to Purchase from Government Supply Sources

(Contractor's Name)

(Contractor's Address)

1. You are hereby authorized to use Government sources in performing Contract No. _____ for the Department of _____, as follows: (Insert applicable purchasing authority given to the contractor.)

2.a. Purchase Orders Under Federal Supply Schedules or Personal Property Rehabilitation Price Schedules. Place orders in accordance with the terms and conditions of the attached Schedule(s) and this authorization. Attach a copy of this authorization to the order (unless a copy was previously furnished to the Federal Supply Schedule or Personal Property Rehabilitation Price Schedule contractor). Insert the following statement in the order: This order is placed under written authorization from _____, dated _____ (*_____). In the event of any inconsistency between the terms and conditions of this order and those of the Federal Supply Schedule or Personal Property Rehabilitation Price Schedule contract, the latter will govern.

b. Requisitioning from the General Services Administration (GSA) or the Department of Defense (DoD). Place orders in accordance with this authorization and, as appropriate, the:

(1) Federal Standard Requisitioning and Issue Procedures (FEDSTRIP) (GSA FEDSTRIP Operating Guide: FPMR 101-26.2 (41 CFR 101-26.2); copies are available from the Superintendent of Documents, Government Printing Office, Washington, DC 20402); or

(2) Military Standard Requisitioning and Issue Procedures (MILSTRIP) (DoD 4000.25-1-M; copies are available from the Defense Logistics Agency, ATTN: DLA-XPD, Bldg., 6, Dr. 21, Cameron Station, Alexandria, VA 22304-6100).

3. * * *

4. This authority is not transferable or assignable.

5. The DoD Activity Address Directory (DoDAAD))(DoD 4000.25-6-M) Activity Address Code** to which this Authorization applies is _____.

6. This Authorization expires _____.

(Contracting Officer)

*Insert "a copy of which is attached," "a copy of which you have on file," or other suitable language, as appropriate.

**The sponsoring service assumes responsibility for monitoring and controlling all activity address codes used in the letters of authority.

***Insert other provisions, as necessary.

(3)(ii) In addition to the procedure and and form authorized by FAR 51 102(e)(3)(ii), contractors may use the DD Form 1155 when requisitioning from the Department of Veterans Affairs.

251.103 Ordering from Government supply sources.

(b) *Contracting agency* means the contracting officer.

251.106 Title.

(b) For DoD, title to property having an acquisition cost of $5,000 or less shall vest in the contractor under the circumstances described in FAR 51.106(b).

251.107 Contract clause.

Use the clause at 252.251-7000, Ordering From Government Supply Sources, in solicitations and contracts which include the clause at FAR 52.251-1, Government Supply Sources.

Subpart 251.2—Contractor Use of Interagency Fleet Management System (IFMS) Vehicles

251.202 Authorization.

(a)(2)(A) See FAR 28.307-2(c) for policy on contractor insurance.

(B) See FAR 28.308 for policy on self-insurance.

(C) See FAR 31.205-19 for allowability of insurance costs.

(5) Paragraph (d) of the clause at 252.251-7001 satisfies the requirement of FAR 51 .202(a)(5) for a written statement.

251.205 Contract clause.

Use the clause at 252.251-7001, Use of Interagency Fleet Management System (IFMS) Vehicles and Related Services, in solicitations and contracts which include the clause at FAR 52.251-2,

Interagency Fleet Management System (IFMS) Vehicles and Related Services.

15. The authority for 48 CFR part 252 continues to read as follows:

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, FAR subpart 1.3.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.203-7000 [Removed]

16. Section 252.203-7000 is removed.

17. Section 252.203-7002 is redesignated as section 252.203-7000 and revised to read as follows:

252.203-7000 Statutory Prohibitions on Compensation to Former Department of Defense Employees.

As prescribed in 203.170-4, use the following clause:

Statutory Prohibition on Compensation to Former Department of Defense Employees (Feb 1991)

(a) Definitions.

As used in the clause—

Armed Forces means the uniformed military services, excluding the U.S. Coast Guard.

Compensation means any payment, gift, benefit, reward, favor, or gratuity which is provided directly or indirectly for services rendered by the person accepting such payment, gift, benefit, reward, favor, or gratuity, and which has a fair market value in excess of $250. Compensation is indirectly provided if it is paid to an entity other than the individual, specifically in exchange for services performed by the individual.

Defense contractor means an entity (including affiliates and subsidiaries which clearly engage in the performance of Department of Defense (DoD) contracts) that contracts directly with the DoD to supply goods or services. "Defense contractor" does not include a state or local government.

Designated Agency Ethics Official means a DoD officer or employee who has been appointed to administer the provisions of the Ethics in Government Act, as amended.

Former DoD Employee means a person who served in the DoD in a civilian position for which the rate of pay was equal to or greater than the minimum rate of pay for grade GS-13 of the General Schedule, or served in the Armed Forces in a pay grade of 04 or higher.

Former DoD Official means—

(1) A former DoD employee who spent the majority of working days during the last 2 years of DoD service performing a procurement function relating to:

(i) A DoD contract, at a site or plant that was owned or operated by the Contractor, and which was the principal location of such person's performance of that procurement function; or

(ii) A major defense system and, in the performance of such function, participated on any occasion personally and substantially in a manner involving decision making responsibilities with respect to a contract for that system through contact with the Contractor;

(2) An individual who served in a civilian position for which the rate of pay is equal to or greater than the minimum rate of pay for a Senior Executive Service position or other executive position at the same or higher level, and an individual who served in the Armed Forces in the pay grade of 07 or higher, if such individual during the last 2 years of DoD service—

(i) Acted as one of the primary Government representatives in the negotiation with a defense contractor of a DoD contract in an amount in excess of $10 million; or

(ii) Acted as one of the primary Government representatives in the negotiation of a settlement of an unresolved claim of such a defense contractor in an amount in excess of $10 million. An unresolved claim shall be, for the purposes of this section, valued by the greater of the amount of the claim or the amount of the settlement.

Major defense contractor means any business entity which, during the Government fiscal year preceding the Government fiscal year in which compensation was first provided to a former DoD employee, was awarded DoD contracts in a total amount of $10 million or more.

Major defense system means a combination of elements that will function together to produce the capability required to fulfill a mission need. Elements may include hardware, equipment, software, or any combination thereof, but exclude construction or other improvements to real property. A system shall be considered a major defense system if—

(1) The DoD is responsible for the system and the total expenditures (based on fiscal year 1980 constant dollars) for research, development, test and evaluation for the system, are estimated to exceed $75 million or the eventual total expenditure for procurement is estimated to exceed $300 million; or

(2) The system is designated a major system by the head of the agency responsible for the system.

Primary Government representative means, if more than one Government representative is involved in any particular transaction, the official or officials supervising the Government's effort in the matter. To act as a "representative" requires personal and substantial participation in the transaction, by personal presence, telephone conversation, or similar involvement with representatives of a contractor.

Procurement-related function (or *procurement function*) means any function relating to—

(1) The negotiation, award, administration, or approval of a contract;

(2) The selection of a contractor;

(3) The approval of a change in a contract;

(4) The performance of quality assurance, operational and developmental testing, the approval of payment, or auditing under a contract; or

(5) The management of a procurement program.

(b) Prohibition on compensation.

(1) 10 U.S.C. 2397b and 2397c prohibit a major defense contractor from offering or providing any compensation valued in excess of $250 to a former DoD official who left DoD service on or after April 16, 1987, and who, while employed by DoD, performed procurement-related functions in connection with that defense contractor. This prohibition runs for the 2-year period beginning on the date of the official's separation from service in DoD.

(2) The Contractor, if a major defense contractor, agrees not to provide, for the 2-year period, any compensation to the former DoD official.

(3) DoD employees may request from their Designated Agency Ethics Official (DAEO) a written opinion on the applicability of 10 U.S.C. 2397b prior to the acceptance of compensation. If the opinion of the DAEO is that the law is not applicable, and that the individual may accept compensation from the Contractor, there shall be a conclusive presumption that the offering and the acceptance of such compensation is not a violation of the statute.

(c) Report concerning former DoD employees.

(1) The Contractor shall submit a separate written report, as described in paragraph (c)(2) of this clause, for each calendar year covered by this contract (extending through final payment) if the calendar year commenced after the end of a Government fiscal year in which the Contractor was awarded one or more DoD contracts aggregating $10 million or more. In multidivisional corporations, the corporate headquarters, and each segment which contracts directly with the Government, shall report separately. Each report shall list those persons employed or otherwise compensated, who are former DoD employees who left service on or after April 16, 1987, if—

(i) They were compensated by the Contractor during the reporting period; and

(ii) The compensation was provided within 2 years after the person left service in the DoD.

(2) The report shall contain:

(i) Each person's name and the agency in which the person was employed or served on active duty during the last 2 years of service with DoD;

(ii) Each person's job title(s) during the last 2 years of service with DoD, and a list of major defense systems on which each person performed any work;

(iii) A complete description (exclusive of proprietary information) of any work that each person is performing, or did perform, on behalf of the Contractor during the calendar year covered by the report. If the work is classified, the Contractor may use a generalized description which will not compromise its classified nature;

(iv) An identification of each major defense system on which each individual has performed any work on behalf of the Contractor.

(3) Submit each report not later than April 1 of the year following the end of the calendar year for which the report is being made. Send reports to the Office of the Assistant General Counsel (Legal Counsel), Standards of Conduct Office, ATTN: OAGC/LC, Pentagon, Washington, DC 20301-1600.

(4) A properly executed DD Form 1787 (Employment, Report of DoD and Defense Related) may be submitted to satisfy the reporting requirement as to any single person.

(5) The Contractor need not submit duplicate reports to the Government. Submission of a report meeting the requirements of this clause, under another, concurrent contract with DoD will satisfy the reporting requirement of this contract.

(d) Penalties for failure to comply.

(1) *Civil fines.* A Contractor who knowingly offers or provides any compensation to a former DoD official in violation of the statute, and who knew or should have known that the acceptance of such compensation would be in violation of such statute, shall be subject to a civil fine, not to exceed $500,000.

(2) *Liquidated damages.* (i) For each knowing violation of the statutory prohibition on providing compensation, the Contractor agrees to pay to the Government as liquidated damages the greater of either $100,000, or three times the total amount of compensation paid by the Contractor to the former DoD official during the period in which such compensation was in violation of the statutory prohibition.

(ii) Liability for liquidated damages under this clause survives final payment under this contract and may be recouped against payments due under other contracts with the Contractor.

(iii) Liquidated damages will be computed based upon the number of actual violations by the Contractor, and not on the number of contracts in which this clause appears.

(3) *Administrative penalty.* If the Contractor knowingly fails to file a report in accordance with paragraph (c) of this clause, the Contractor shall be subject to an administrative penalty not to exceed $10,000. The final determination of the penalty to be charged to the Contractor shall be made by the Secretary of Defense or designee after the Contractor is afforded an opportunity for an agency hearing on the record in accordance with agency hearing procedures. The Secretary's determination shall form a part of the record and shall be subject to judicial review under chapter 7 of title 5, United States Code.

(e) The rights and remedies under this clause are in addition to, and do not limit, any rights afforded the Government under this contract or as otherwise provided by law.

(End of clause)

18. Section 252.203–7001 is revised to read as follows:

252.203–7001 Special Prohibition on Employment.

As prescribed in 203.570–5, use the following clause:

Special Prohibition on Employment (FEB 1991)

(a) Definitions.

As used in this clause—

Arising out of a contract with the DoD means any act in connection with—

(1) Attempting to obtain,

(2) Obtaining, or

(3) Performing a contract or subcontract of any agency, department, or component of the Department of Defense (DoD).

Conviction of fraud or any other felony means any conviction for fraud or a felony in violation of state or Federal criminal statutes, whether entered on a verdict or plea, including a plea of *nolo contendere*, for which sentence has been imposed.

Date of conviction means the date judgment was entered against the individual.

(b) 10 U.S.C. 2408 provides that any individual who is convicted after September 29, 1988, of fraud or any other felony arising out of a contract with the DoD is prohibited from:

(1) Working in a management or supervisory capacity on any DoD contract;

(2) Serving on the board of directors of any DoD contractor; or

(3) Serving as a consultant to any DoD contractor.

(c) Unless waived, the prohibition in paragraph (b) of this clause applies for 5 years from the date of conviction.

(d) 10 U.S.C. 2408 further provides that a defense contractor shall be subject to a criminal penalty of not more than $500,000 if the contractor is convicted of knowingly—

(1) Employing a person under a prohibition specified in paragraph (b) of this clause; or

(2) Allowing such a person to serve on the board of directors of the contractor.

(e) In addition to the criminal penalties contained in 10 U.S.C. 2408, the Government may consider other available remedies, such as—

(1) Suspension or debarment;

(2) Cancellation of the contract at no cost to the Government; or

(3) Termination of the contract for default.

(f) The Contractor may submit written requests for waiver of the prohibitions in paragraph (b) to the Contracting Officer. Requests shall clearly identify—

(1) The person involved;

(2) The nature of the conviction and resultant sentence or punishment imposed;

(3) The reasons for the requested waiver; and,

(4) An explanation of why a waiver is in the interest of national security.

(g) The Contractor agrees to include the substance of this clause, including this paragraph (g), appropriately modified to reflect the identity and relationship of the parties, in all subcontracts exceeding $25,000.

(End of clause)

19. Section 252.203–7003 is redesignated as section 252.203–7002 and revised to read as follows:

252.203–7002 Display of DoD Hotline Poster.

As prescribed in 203.7002, use the following clause:

Display of DoD Hotline Poster (FEB 1991)

(a) The Contractor shall display prominently in common work areas within business segments performing work under Department of Defense (DoD) contracts, DoD Hotline Posters prepared by the DoD Office of the Inspector General.

(b) DoD Hotline Posters may be obtained from the DoD Inspector General, ATTN: Defense Hotline, 400 Army Navy Drive, Washington, DC 22202–2884.

(c) The Contractor need not comply with paragraph (a) of this clause if it has established a mechanism, such as a hotline, by which employees may report suspected instances of improper conduct, and instructions that encourage employees to make such reports.

(End of clause)

20. Section 252.219–7000 is revised to read as follows:

252.219–7000 Small Business and Small Disadvantaged Business Subcontracting Plan (DoD Contracts).

As prescribed in 219.708(b), use the following clause:

Small Business and Small Disadvantaged Business Subcontracting Plan (DoD Contracts) (FEB 1991)

This clause supplements the FAR 52.219–9, Small Business and Small Disadvantaged Business Subcontracting Plan, clause of this contract.

(a) Definitions.

Historically black colleges and universities, as used in this clause, means institutions determined by the Secretary of Education to meet the requirements of 34 CFR 608.2.

Minority institutions, as used in this clause, means institutions meeting the requirements of paragraphs (3), (4), and (5) of section 312(b) of the Higher Education Act of 1965 (20 U.S.C. 1058). The term also means any nonprofit research institution that was an integral part of a historically black college or university before November 14, 1986.

(b) Except for company or division-wide commercial products subcontracting plans, the term "small disadvantaged business," when used in the FAR 52.219–9 clause, includes historically black colleges and universities and minority institutions, in addition to small disadvantaged business concerns.

(c) Work under the contract or its subcontracts shall be credited toward meeting the small disadvantaged business concern goal required by paragraph (d) of the FAR 52.219 clause when:

(1) It is performed on Indian lands or in joint venture with an Indian tribe or a tribally owned corporation, and

(2) It meets the requirements of Section 832 of the FY 90 DoD Authorization Act, Pub. L. 101–189.

(d) The master plan approval referred to in paragraph (f) of the FAR 52.219–9 clause is approval by the contractor's cognizant contract administration activity.

(End of clause)

252.219–7001 through 252.219–7003 [Removed]

21. Sections 252.219–7001 through 252.219–7003 are removed.

22. Section 252.219–7005 is redesignated as section 252.219–7001 and revised to read as follows:

252.219-7001 Small Disadvantaged Business Concern Representation (DoD Contracts).

As prescribed in 219.304(b), use the following provision:

Small Disadvantaged Business Concern Representation (DoD Contracts) (FEB 1991)

(a) Definition.

Small disadvantaged business concern, as used in this provision, means a small business concern, owned and controlled by individuals who are both socially and economically disadvantaged, as defined by the Small Business Administration at 13 CFR part 124, the majority of earnings of which directly accrue to such individuals. This term also means a small business concern owned and controlled by an economically disadvantaged Indian tribe or Native Hawaiian organization which meets the requirements of 13 CFR 124.112 or 13 CFR 124.113, respectively. In general, 13 CFR part 124 describes a small disadvantaged business concern as a small business concern—

(1) Which is at least 51 percent unconditionally owned by one or more socially and economically disadvantaged individuals; or

(2) In the case of any publicly owned business, at least 51 percent of the voting stock is unconditionally owned by one or more socially and economically disadvantaged individuals; and

(3) Whose management and daily business operations are controlled by one or more such individuals.

(b) Representations.

Check the category in which your ownership falls—

___Subcontinent Asian (Asian-Indian) American (U.S. citizen with origins from India, Pakistan, Bangladesh, Sri Lanka, Bhutan, or Nepal)

___Asian-Pacific American (U.S. citizen with origins from Japan, China, the Philippines, Vietnam, Korea, Samoa, Guam, U.S. Trust Territory of the Pacific Islands (Republic of Palau), the Northern Mariana Islands, Laos, Kampuchea (Cambodia), Taiwan, Burma, Thailand, Malaysia, Indonesia, Singapore, Brunei, Republic of the Marshall Islands, or the Federated States of Micronesia)

___Black American (U.S. citizen)

___Hispanic American (U.S. citizen with origins from South America, Central America, Mexico, Cuba, the Dominican Republic, Puerto Rico, Spain, or Portugal)

___Native American (American Indians, Eskimos, Aleuts, or Native Hawaiians, including Indian tribes or Native Hawaiian organizations)

___Individual/concern, other than one of the preceding, currently certified for participation in the Minority Small Business and Capital Ownership Development Program under Section 8(a) of the Small Business Act

___Other

(c) Certifications.

Complete the following—

(1) The offeror is___is not___a small disadvantaged business concern.

(2) The Small Business Administration (SBA) has___has not___made a determination concerning the offeror's status as a small disadvantaged business concern. If the SBA has made a determination, the date of the determination was_____and the offeror—

___Was found by SBA to be socially and economically disadvantaged and no circumstances have changed to vary that determination.

___Was found by SBA not to be socially and economically disadvantaged but circumstances which caused the determination have changed.

(d) Notification.

Notify the Contracting Officer before contract award if your status as a small disadvantaged business concern changes.

(e) Penalties and Remedies.

Anyone who misrepresents the status of a concern as a small disadvantaged business for the purpose of securing a contract or subcontract shall—

(1) Be punished by imposition of a fine, imprisonment, or both;

(2) Be subject to administrative remedies, including suspension and debarment; and

(3) Be ineligible for participation in programs conducted under authority of the Small Business Act.

(End of provision)

23. Section 252.219–7006 is redesignated as section 252.219–7002 and revised to read as follows:

252.219–7002 Notice of Small Disadvantaged Business Set-Aside.

As prescribed in 219.508–70, use the following clause:

Notice of Small Disadvantaged Business Set-Aside (FEB 1991)

(a) Definition.

Small disadvantaged business concern, as used in this clause, means a small business concern, owned and controlled by individuals who are both socially and economically disadvantaged, as defined by the Small Business Administration at 13 CFR part 124, the majority of eanings of which directly accrue to such individuals. This term also means a small business concern owned and controlled by an economically disadvantaged Indian tribe or Native Hawaiian organization which meets the requirements of 13 CFR 124.112 or 13 CFR 124.113, respectively.

(b) General.

Offers are solicited only from small disadvantaged business concerns. Offers received from concerns that are not small disadvantaged businesses are nonresponsive and will be rejected.

(c) Agreement.

A small disadvantaged business manufacturer or regular dealer, which submits an offer in its own name, agrees to furnish in performing this contract only end items manufactured or produced by small disadvantaged business concerns in the United States, its territories and possessions, the Commonwealth of Puerto Rico, the U.S. Trust Territory of the Pacific Islands, or the District of Columbia.

(End of clause)

Alternate I (FEB 1991)

As prescribed in 219.508–70, substitute the following paragraph (c) for paragraph (c) of the basic clause:

(c) Agreement.

A small disadvantaged business regular dealer submitting an offer in its own name agrees to furnish in performing this contract only end items manufactured or produced by small business concerns in the United States, its territories and possessions, the Commonwealth of Puerto Rico, the U.S. Trust Territory of the Pacific Islands, or the District of Columbia.

24. Section 252.219–7007 is redesignated as section 252.219–7003 and revised to read as follows:

252.219–7003 Notice of Evaluation Preference for Small Disadvantaged Business Concerns.

As prescribed in 219.7003, use the following clause:

Notice of Evaluation Preference for Small Disadvantaged Business Concerns (FEB 1991)

(a) Definitions.

Historically black colleges and universities, as used in this clause, means institutions determined by the Secretary of Education to meet the requirements of 34 CFR 608.2.

Minority institutions, as used in this clause, means institutions meeting the requirements of paragraphs (3), (4), and (5) of section 312(b) of the Higher Education Act of 1965 (20 U.S.C. 1058). The term also means any nonprofit research institution that was an integral part of a historically black college or university before November 14, 1986.

Small disadvantaged business concern, as used in this clause, means a small business concern, owned and controlled by individuals who are both socially and economically disadvantaged, as defined by the Small Business Administration at 13 CFR part 124, the majority of earnings of which directly accrue to such individuals. This term also means a small business concern owned and controlled by an economically disadvantaged Indian tribe or Native Hawaiian organization which meets the requirements of 13 CFR 124.112 or 13 CFR 124.113, respectively.

(b) Evaluation preference.

(1) Offers will be evaluated by adding a factor of ten percent to the price of all offers, except—

(i) Offers from small disadvantaged business concerns;

(ii) Offers from historically black colleges and universities or minority institutions;

(iii) Offers of—

(A) Eligible products under the Trade Agreements Act when the dollar threshold for application of the Act is exceeded;

(B) Qualifying country end products; and

(C) Offers where application of the factor would be inconsistent with a Memorandum of Understanding or other international agreement with a foreign government.

(2) The ten percent factor will be applied on a line item by line item basis or to any group of items on which award may be made. Other evaluation factors described in the

solicitation will be applied before application of the ten percent factor. The ten percent factor will not be applied if using the preference would cause the contract award to be made at a price which exceeds the fair market price by more than ten percent.

(c) Waiver of evaluation preference.

A small disadvantaged business, historically black college or university, or minority institution offeror may elect to waive the preference, in which case the ten percent factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of this clause do not apply to offers which waive the preference.

___ Offeror elects to waive the preference

(d) Agreements.

(1) A small disadvantaged business concern, historically black college or university, or minority institution offeror, which did not waive the preference, agrees that in performance of the contract, in the case of a contract for—

(i) Services, except construction, at least 50 percent of the cost of personnel for contract performance will be spent for employees of the concern.

(ii) Supplies, at least 50 percent of the cost of manufacturing, excluding the cost of materials, will be performed by the concern.

(iii) General construction, at least 15 percent of the cost of the contract, excluding the cost of materials, will be performed by employees of the concern.

(iv) Construction by special trade contractors, at least 25 percent of the cost of the contract, excluding the cost of materials, will be performed by employees of the concern.

(2) A small disadvantaged business, historically black college or university, or minority institution regular dealer submitting an offer in its own name agrees to furnish in performing this contract only end items manufactured or produced by small disadvantaged business concerns, historically black colleges or universities, or minority institutions in the United States, its territories and possessions, the Commonwealth of Puerto Rico, the U.S. Trust Territory of the Pacific Islands, or the District of Columbia.

(3) Upon request, a historically black college or university or minority institution offeror will provide the Contracting Officer evidence that it has been determined to be an HBCU or MI by the Secretary of Education.

(End of clause)

Alternate I (FEB 1991)

As prescribed in 219.7003, substitute the following paragraph (d)(2) for paragraph (d)(2) of the basic clause:

(d)(2) A small disadvantaged business, historically black college or university, or minority institution regular dealer submitting an offer in its own name agrees to furnish in performing this contract only end items manufactured or produced by small business concerns, historically black colleges or universities, or minority institutions in the United States, its territories and possessions, the Commonwealth of Puerto Rico, the U.S. Trust Territory of the Pacific Islands, or the District of Columbia.

252.219-7004 [Removed]

25. Section 252.219-7004 is removed.

26. Section 252.219-7010 is redesignated as section 252.219-7004 and revised to read as follows:

252.219-7004 Notice of Partial Small Business Set-Aside With Preferential Consideration for Small Disadvantaged Business Concerns.

As prescribed in 219.508(d)(S-70), use the following clause:

Notice of Partial Small Business Set-Aside With Preferential Consideration for Small Disadvantaged Business Concerns (FEB 1991)

(a) Definitions.

Labor surplus area, as used in this clause, means a geographical area identified by the Department of Labor as an area of labor surplus.

Labor surplus area concern, as used in this clause, means a concern that, together with its first tier subcontractors, will perform substantially in labor surplus areas.

Perform substantially in labor surplus areas, as used in this clause, means that the costs incurred under the contract on account of manufacturing, production, and performance of services in labor surplus areas exceed 50 percent of the contract price.

Small business concern, as used in this clause, means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the size standards in this solicitation.

Small disadvantaged business concern, as used in this clause, means a small business concern, owned and controlled by individuals who are both socially and economically disadvantaged, as defined by the Small Business Administration at 13 CFR part 124, the majority of earnings of which directly accrue to such individuals. This term also means a small business concern owned and controlled by an economically disadvantaged Indian tribe or Native Hawaiian organization which meets the requirements of 13 CFR 124.112 or 13 CFR 124.113, respectively.

(b) General.

A portion of this requirement, identified elsewhere in this solicitation, has been set-aside for award to one or more small business concerns. After offers for the non-set-aside portion have been evaluated, negotiations will be conducted for the set-aside portion.

(1) Offers on the non-set-aside portion will be evaluated and award made in accordance with the other provisions of this solicitation.

(2) The set-aside portion will be negotiated, in accordance with this clause, with small business concerns which submitted offers on the non-set-aside portion.

(c) Award of the set-aside portion.

(1) Small business offerors on the non-set-aside portion will be selected for negotiation of the set-aside portion based on their standing— first in terms of group and then in terms of lowest responsive offer on the non-set-aside portion.

(i) Group 1—Small disadvantaged business concerns which are also labor surplus area concerns.

(ii) Group 2—Small business concerns which are also labor surplus area concerns.

(iii) Group 3—Other small disadvantaged business concerns.

(iv) Group 4—Other small business concerns.

(2) The set-aside portion will be awarded at the highest unit price(s) in the contract(s) for the non-set-aside portion, adjusted to reflect transportation and other costs appropriate for the selected contractor(s), except—

(i) Award of the set-aside portion to a small disadvantaged business concern will be at the lower of—

(A) The price offered by the concern on the non-set-aside portion; or

(B) A price that does not exceed the award price on the non-set-aside portion by more than ten percent.

(ii) When the highest unit price(s) in the contract(s) is for a foreign end product, the set-aside portion will be awarded at that price as adjusted in evaluating the offer under Buy American procedures.

(iii) Discount terms used in evaluation of the highest non-set-aside award price will apply to the set-aside award price.

(3) If negotiations are not successful for any part of the set-aside portion, the set-aside will be dissolved for that part and the requirement will be resolicited.

(d) Token offers.

The Government reserves the right to not consider token offers or offers designed to secure an unfair advantage over other offerors eligible for the set-aside portion.

(e) Eligibility for preference as a labor surplus area concern.

Small business or small disadvantaged business offerors which claim preference for the set-aside portion as a labor surplus area concern, list the labor surplus area location(s) of offeror or first tier subcontractors, which account for more than 50 percent of the contract price.

Name of Company:

Street Address:

City/County:

State:

(f) Agreements.

(1) If awarded a contract as a small disadvantaged business-labor surplus area concern or as a small business-labor surplus area concern, the offeror—

(i) Will perform the contract, or cause it to be performed, substantially in areas classified as labor surplus areas.

(ii) If the contract is in excess of $25,000, will submit a report to the Contracting Officer within 30 days after award that contains the following information—

(A) The dollar amount of the contract.

(B) Identification of each labor surplus area in which contract and subcontract performance is taking or will take place.

(C) The total costs incurred and to be incurred under the contract in each of the labor surplus areas by the contractor and first tier subcontractors.

(D) The total dollar amount attributable to performance in labor surplus areas.

(2) A manufacturer or regular dealer, which claims preference as a small disadvantaged business and submits an offer in its own name, agrees to furnish in performing this contract only end items manufactured or produced by small disadvantaged business concerns in the United States, its territories and possessions, the Commonwealth of Puerto Rico, the U.S. Trust Territory of the Pacific Islands, or the District of Columbia.

(End of clause)

Alternate I (FEB 1991)

As prescribed in 219.508(d)(S-70), substitute the following paragraph (f)(2) for paragraph (f)(2) of the basic clause:

(f)(2) A regular dealer, which claims preference as a small disadvantaged business and submits an offer in its own name, agrees to furnish in performing this contract only end items manufactured or produced by small business concerns in the United States, its territories and possessions, the Commonwealth of Puerto Rico, the U.S. Trust Territory of the Pacific Islands, or the District of Columbia.

252.219-7008 [Removed]

27. Section 252.219-7008 is removed.

28. Section 252.219-7009 is redesignated as section 252.219-7005 and revised to read as follows:

252.219-7005 Incentive for Subcontracting with Small Businesses, Small Disadvantaged Businesses, Historically Black Colleges and Universities, and Minority Institutions.

As prescribed in 219.708(c)(1), use the following clause:

Incentive for Subcontracting With Small Businesses, Small Disadvantaged Businesses, Historically Black Colleges and Universities, and Minority Institutions (FEB 1991)

(a) If the Contractor exceeds the small disadvantaged business, historically black college and university, minority institution goal of its subcontracting plan, at completion of contract performance, the Contractor will receive (Insert appropriate number between 1 and 10) percent of the excess.

(b) The Contractor will not receive this incentive if the Contracting Officer determines that exceeding the goal was not due to the Contractor's efforts (e.g., a subcontractor cost overrun or award of subcontracts planned but not disclosed in the subcontracting plan). Determinations made under this paragraph are not subject to the Disputes clause.

(c) If this is a cost contract, the limitations in FAR subpart 15.9 may not be exceeded.

(d) This clause does not apply if the subcontracting plan is a plant, division, or company-wide commercial products plan.

(End of clause)

Alternate I (FEB 1991)

As prescribed in 219.708(c)(1), add the following paragraph (b) to the basic clause and renumber the existing paragraphs (b), (c), and (d) as (c), (d), and (e).

(b) If the Contractor exceeds the small business goal of its subcontracting plan, at completion of contract performance, the Contractor will receive (Insert appropriate number between 1 and 10) percent of the excess.

252.219-7011 through 252.219-7014 [Removed]

29. Sections 252.219-7011 through 252.219-7014 are removed.

30. Section 252.219-7015 is redesignated as section 252.219-7006 and revised to read as follows:

252.219-7006 Small Business and Small Disadvantaged Business Subcontracting Plan (Test Program).

As prescribed in 219.708(b)(1), use the following clause:

Small Business and Small Disadvantaged Business Subcontracting Plan (Test Program)(FEB 1991)

(a) Definition.

Subcontract, as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for performance of the contract or subcontract.

(b) The Offeror's comprehensive small business subcontracting plan and its successors, which are authorized by and approved under the test program of Section 834 of Public Law 101-189, shall be included in and made a part of the resultant contract. Upon expulsion from the test program or expiration of the test program, the Contractor shall negotiate an individual subcontracting plan for all future contracts that meet the requirements of Section 211 of Public Law 95-507.

(c) The Contractor shall submit Standard Form 295, Summary Subcontract Report, in accordance with the instructions on the form, except (1) Items 17 and 18 shall not be completed; (2) Item 16, Remarks, shall be completed to include small business and small disadvantaged business goals, actual accomplishments, and percentages and small business and small disadvantaged business goals, actual accomplishments, and percentages for each of the two designated industry categories.

(d) The failure of the Contractor or subcontractor to comply in good faith with (1) the clause of this contract entitled "Utilization of Small Business Concerns and Small Disadvantaged Business Concerns," or (2) an approved plan required by this clause, shall be a material breach of the contract.

(End of clause)

31. Section 252.219-7016 is redesignated as section 252.219-7007 and revised to read as follows:

252.219-7007 Liquidated Damages—Small Business Subcontracting Plan (Test Program).

As prescribed in 219.708(b)(2), use the following clause:

Liquidated Damages—Small Business Subcontracting Plan (Test Program)(Feb 1991)

(a) Definition.

Failure to make a good faith effort to comply with the comprehensive subcontracting plan, as used in this clause, means a willful or intentional failure to perform in accordance with the requirements of the comprehensive subcontracting plan approved under the test program authorized by Section 834 of Public Law 101-189, or willful or intentional action to frustrate the plan.

(b) If, at the close of the fiscal year for which the plan applies or at the close of a subsequent fiscal year for which a successor plan applies, the Contractor has failed to meet its subcontracting goals and the Contracting Officer decides in accordance with paragraph (c) of this clause that the Contractor failed to make a good faith effort to comply with its comprehensive subcontracting plan, the Contractor shall pay the Government liquidated damages in an amount equal to the actual dollar amount by which the Contractor failed to achieve each subcontract goal.

(c) Before the Contracting Officer makes a final decision that the Contractor has failed to make such good faith effort, the Contracting Officer shall give the Contractor written notice specifying the failure and permitting the Contractor to demonstrate what good faith efforts have been made. Failure to respond to the notice may be taken as an admission that no valid explanation exists. If, after consideration of all the pertinent data, the Contracting Officer finds that the Contractor failed to make a good faith effort to comply with the comprehensive subcontracting plan, the Contracting Officer shall issue a final decision to that effect and require that the Contractor pay the Government liquidated damages as provided in paragraph (b) of this clause.

(d) The Contracting Officer of the agency that originally approved the comprehensive subcontracting plan will exercise the functions of the Contracting Officer under this clause on behalf of all Department of Defense departments and agencies that awarded contracts covered by the Contractor's comprehensive subcontracting plan.

(e) The Contractor shall have the right of appeal, under the clause in this contract entitled Disputes, from any final decision of the Contracting Officer.

(f) Liquidated damages shall be in addition to any other remedies that the Government may have.

(End of clause)

252.220-7000 and 252.220-7001 [Removed]

32. Sections 252.220-7000 and 252.220-7001 are removed.

33. Section 252.226-7000 is revised to read as follows:

252.226-7000 Notice of Historically Black College or University and Minority Institution Set-Aside.

As prescribed in 226.7008(a), use the following clause:

Notice of Historically Black College or University and Minority Institution Set-Aside (FEB 1991)

(a) Definitions.

Historically black colleges and universities, as used in this clause, means institutions determined by the Secretary of Education to meet the requirements of 34 CFR 608.2.

Minority institutions, as used in this clause, means institutions meeting the requirements of paragraphs (3), (4), and (5) of Section 312(b) of the Higher Education Act of 1965 (20 U.S.C. 1058). The term also means any nonprofit research institution that was an integral part of a historically black college or university before November 14, 1986.

(b) General.

(1) Offers are solicited only from historically black colleges or universities and minority institutions.

(2) Any award resulting from this solicitation will be made only to an offeror which is a historically black college or university or a minority institution both at the time of submission of its offer and at contract award.

(c) Agreements.

The offeror will—

(1) Perform at least 50 percent of the cost of contract performance incurred for personnel with its own employees; and

(2) Upon request by the Contracting Officer, provide evidence prior to award that the Secretary of Education has determined the offeror to be a historically black college or university or minority institution.

(End of clause)

34. Section 252.226-7001 is revised to read as follows:

252.226-7001 Historically Black College or University and Minority Institution Certification.

As prescribed in 226.7008(b), use the following provision:

Historically Black College or University and Minority Institution Certification. (FEB 1991)

(a) Definitions.

Historically black colleges and universities, as used in this provision, means institutions determined by the Secretary of Education to meet the requirements of 34 CFR 608.2.

Minority institutions, as used in this provision, means institutions meeting the requirements of paragraphs (3), (4), and (5) of Section 312(b) of the Higher Education Act of 1965 (20 U.S.C. 1058). The term also means any nonprofit research institution that was an integral part of a historically black college or university before November 14,1986.

(b) Certification.

The offeror certifies that it is—

_____ A historically black college or university

_____ A minority institution

(c) Notification.

Notify the Contracting Officer before award if your status as a historically black college or university or minority institution changes.

(End of provision)

252.229-7000 [Removed]

35. Section 252.229-7000 is removed.

36. Section 252.231-7000 is revised to read as follows:

252.231-7000 Supplemental Cost Principles.

As prescribed in 231.270, use the following clause:

Supplemental Cost Principles (FEB 1991)

When the allowability of costs under this contract is determined in accordance with subpart 31.2 of the Federal Acquisition Regulation (FAR), allowability shall also be determined in accordance with subpart 231.2 of the Defense FAR Supplement, in effect on the date of this contract.

(End of clause)

37. Section 252.231-7001 is revised to read as follows:

252.231-7001 Penalties for Unallowable Costs.

As prescribed in 231.7004, use the following clause:

Penalties for Unallowable Costs (FEB 1991)

(a) Contractors which include unallowable costs in a final indirect cost rate proposal or any other proposal that includes incurred and accrued indirect costs are subject to assessment of penalties. The penalties are prescribed in 10 U.S.C. 2324, which is implemented in subpart 231.70 of the Defense FAR Supplement.

(b) The Contractor shall not include in any proposal any cost which is unallowable as defined in FAR part 31.

(c) If the Contracting Officer determines by clear and convincing evidence that a cost submitted by the Contractor in its proposal is unallowable, the Contractor shall be assessed a penalty equal to—

(1) The amount of the disallowed cost allocated to this contract; plus

(2) Simple interest, to be computed—

(i) On the amount the Contractor was paid (whether as a progress or billing payment) in excess of the amount to which the Contractor was entitled.

(ii) Using the applicable rate effective for each 6 month interval prescribed by the Secretary of the Treasury pursuant to Public Law 92-41(85 Stat. 97).

(d) If the Contracting Officer determines that a cost submitted by the Contractor in its proposal includes a cost previously determined to be unallowable for the Contractor, then the Contractor will be assessed an additional penalty in an amount equal to two times the amount of the unallowable cost.

(e) Determinations under (c) and (d) of this clause are final decisions within the meaning of the Contract Disputes Act of 1978 (41 U.S.C. 604, *et seq.*).

(f) The Government is entitled to assess an additional penalty of not more than $10,000 per proposal, if any penalty is assessed under paragraphs (c) or (d) of this clause.

(g) Contractor submission of unallowable costs is also subject to the provisions of 18 U.S.C. 287 and 31 U.S.C. 3729.

(h) Payment by the Contractor of any penalty assessed under this clause does not constitute repayment to the Government of any unallowable cost which has been paid by the Government to the Contractor.

(End of clause)

252.231-7002 [Removed]

38. Section 252.231-7002 is removed.

39. Section 252.233-7000 is revised to read as follows:

252.233-7000 Certification of Claims and Requests for Adjustment or Relief.

As prescribed in 233.7000, use the following clause:

Certification of Claims and Requests for Adjustment or Relief (FEB 1991)

(a) Any contract claim, request for equitable adjustment to contract terms, request for relief under Public Law 85-804, or other similar request exceeding $100,000 shall bear, at the time of submission, the following certificate given by a senior company official in charge at the plant or location involved:

I certify that the claim is made in good faith, that the supporting data are accurate and complete to the best of my knowledge and belief; and that the amount requested accurately reflects the contract adjustment for which the Contractor believes the Government is liable.

_____

(Official's Name)

_____

(Title)

(b) The certification in paragraph (a) of this clause requires full disclosure of all relevant facts, including cost and pricing data.

(c) The certification requirement in paragraph (a) of this clause does not apply to:

(1) Requests for routine contract payments; for example, those for payment for accepted supplies and services, routine vouchers under cost-reimbursement type contracts, and progress payment invoices; or

(2) Final adjustments under incentive provisions of contracts.

(d) In those instances where the claim arises as a result of a contract dispute, a single certification, using the language prescribed by the Contract Disputes Act but signed by a senior company official in charge at the plant or location involved, will satisfy the certification requirements of both this clause and Section 6(c) of the Contract Disputes Act, Pub. L. 95-563.

(e) If this is a request for equitable adjustment under a substantially completed contract or a completed contract, the certification will be expanded to include the following:

This claim includes only costs for performing the alleged change, and does not include any costs which have already been reimbursed or which have been separately claimed. All indirect costs claimed are properly allocable to the alleged change in

accordance with applicable acquisition regulations. I am aware that the submission of a false claim to the Government can result in the assessment of significant penalties and fines, and that no proof of specific intent to defraud is required in either a civil or criminal prosecution for the submission of a false claim.

(End of clause)

40. Section 252.243–7000 is revised to read as follows:

252.243–7000 Engineering Change Proposals.

As prescribed in 243.205–70, use the following clause:

Engineering Change Proposals (FEB 1991)

(a) The Contracting Officer may ask the Contractor to prepare engineering change proposals for engineering changes within the scope of this contract. Upon receipt of a written request from the Contracting Officer, the Contractor shall prepare and submit an engineering change proposal in accordance with the instructions of _____*.

(b) The Contractor may initiate engineering change proposals. Contractor initiated engineering change proposals shall include a "not to exceed" price** or a "not less than" price** and delivery adjustment. If the Contracting Officer orders the engineering change, the increase shall not exceed nor the decrease be less than the "not to exceed" or "not less than" amounts***.

(c) When the price** of the engineering change is $100,000 or more, the Contractor shall submit

(1) A completed SF 1411, Contract Pricing Proposal Cover Sheet, and

(2) At the time of agreement on price**, a signed Certificate of Current Cost or Pricing Data.

(End of clause)

Alternate I (FEB 1991)

As prescribed in 243.205–70, add the following paragraph (d) to the basic clause:

(d) If the price** of a Contractor initiated engineering change is _____**** or less, the change, if ordered, shall be made at no adjustment in the contract price**.

*Insert MIL–STD–480 or MIL–STD–481.

**Use a term suitable for the type of contract.

***In cost reimbursement type contracts, replace this sentence with the following: "Change orders issued under the Changes clause of this contract are not an authorization to exceed the estimated cost in the schedule unless there is a statement in the change order, or other contract modification, increasing the estimated cost."

****Insert a percentage of the contract price or a dollar amount.

41. Section 252.243–7001 is revised to read as follows:

252.243–7001 Pricing of Contract Modifications.

As prescribed in 243.205–71, use the following clause:

Pricing of Contract Modifications (FEB 1991)

When costs are a factor in any price adjustment under this contract, the contract cost principles and procedures in FAR part 31 and DFARS part 231, in effect on the date of this contract, apply.

(End of clause)

42. Section 252.248–7000 is added to part 252 to read as follows:

252.248–7000 Preparation of Value Engineering Change Proposals.

As prescribed in 248.270, use the following clause and insert either "MIL–STD–480" or "MIL–STD–481 (Short form)" in the blank:

Preparation of Value Engineering Change Proposals (FEB 1991)

Prepare value engineering change proposals, for submission pursuant to the value engineering clause of this contract, in the format prescribed by the latest version of _____.

(End of clause)

43. Section 252.251–7000 is revised to read as follows:

252.251–7000 Ordering From Government Supply Sources.

As prescribed in 251.107, use the following clause:

Ordering From Government Supply Sources (FEB 1991)

(a) When placing orders under Federal Supply Schedules or Personal Property Rehabilitation Price Schedules, the Contractor shall follow the terms of the applicable schedule and authorization. Include in each order:

(1) A copy of the authorization (unless a copy was previously furnished to the Federal Supply Schedule or Personal Property Rehabilitation Price Schedule contractor).

(2) The following statement:

This order is placed under written authorization from _____ dated _____.

In the event of any inconsistency between the terms and conditions of this order and those of your Federal Supply Schedule contract or Personal Property Rehabilitation Price Schedule contract, the latter will govern.

(3) The completed address(es) to which the Contractor's mail, freight, and billing documents are to be directed.

(b) If a Federal Supply Schedule contractor refuses to honor an order placed by a Government contractor under an agency authorization, the Contractor shall report the circumstances to the General Services Administration, FFN, Washington, DC 20406, with a copy to the authorizing office.

(c) When placing orders under nonmandatory schedule contracts and requirements contracts, issued by the General Services Administration (GSA) Office of Information Resources Management, for automated data processing equipment, software and maintenance, communications equipment and supplies, and teleprocessing services, the Contractor shall follow the terms of the applicable contract and the procedures in paragraph (a) of this clause.

(d) When placing orders for Government stock, the Contractor shall—

(1) Comply with the requirements of the Contracting Officer's authorization, using FEDSTRIP or MILSTRIP procedures, as appropriate;

(2) Use only the GSA Form 1948–A, Retail Services Shopping Plate, when ordering from GSA Self-Service Stores;

(3) Order only those items required in the performance of Government contracts; and

(4) Pay bills from Government supply sources promptly.

(e) Only the Contractor may request authorization for subcontractor use of Government supply sources. The Contracting Officer will not grant authorizations for subcontractor use without approval of the Contractor.

(End of clause)

44. Section 252.251–7001 is revised to read as follows:

252.251–7001 Use of Interagency Fleet Management System (IFMS) Vehicles and Related Services.

As prescribed in 251.205, use the following clause:

Use of Interagency Fleet Management System (IFMS) Vehicles and Related Services (FEB 1991)

(a) The Contractor, if authorized use of IFMS vehicles, shall submit requests for five or fewer vehicles and related services in writing to the appropriate General Services Administration (GSA) Regional Customer Service Bureau, Attention: Motor Equipment Activity. Submit requests for more than five vehicles to GSA headquarters: General Services Administration, FTM, Washington, DC 20406. Include the following in each request:

(1) Two copies of the agency authorization to obtain vehicles and related services from GSA.

(2) The number of vehicles and related services required and the period of use.

(3) A list of the Contractor's employees authorized to request vehicles and related services.

(4) A list of the makes, models, and serial numbers of Contractor-owned or leased equipment authorized to be serviced.

(5) Billing instructions and address.

(b) The Contractor should make requests for any unusual quantities of vehicles as far in advance as possible.

(c) The Contractor shall establish and enforce suitable penalties for employees who use or authorize the use of Government vehicles for other than performance of Government contracts.

(d) The Contractor shall assume, without the right of reimbursement from the Government, the cost or expense of any use of IFMS vehicles and services not related to the performance of the contract.

(e) Only the Contractor may request authorization for subcontractor use of IFMS vehicles. The Contracting Officer will not grant authorization for subcontractor use without approval of the Contractor.

(End of clause)

Appendix Q to Chapter 2—[Removed]

45. Appendix Q to chapter 2 is removed.

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Tuesday
August 14, 1990

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 358

Wart Remover Drug Products for Over-the-Counter Human Use; Final Monograph; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 358

[Docket No. 80N-0238]

RIN 0905-AA06

Wart Remover Drug Products for Over-the-Counter Human Use; Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) wart remover drug products are generally recognized as safe and effective and not misbranded. FDA is issuing this final rule after considering public comments on the agency's proposed regulation, which was issued in the form of a tentative final monograph, and all new data and information on wart remover drug products that have come to the agency's attention. This final monograph is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: August 14, 1990.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 3, 1980 (45 FR 65609), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC wart remover drug products, together with the recommendations of the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in this drug class. Interested persons were invited to submit comments by January 2, 1981. Reply comments in response to comments filed in the initial comment period could be submitted by February 2, 1981.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, after deletion of a small amount of trade secret information.

The agency's proposed regulation, in the form of a tentative final monograph, for OTC wart remover drug products was published in the Federal Register of September 3, 1982 (47 FR 39102). Interested persons were invited to file by November 2, 1982, written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the proposal. Interested persons were invited to file comments on the agency's economic impact determination by July 27, 1987. New data could have been submitted until March 27, 1988, and comments on the new data until May 27, 1988.

In the Federal Register of March 27, 1987 (52 FR 9992), the agency issued a reproposal of the tentative final monograph for OTC wart remover drug products to reflect new data and information. The agency stated that data and comments submitted in response to the tentative final monograph for OTC wart remover drug products, published in the Federal Register of September 3, 1982 (47 FR 39102), had not yet been evaluated by the agency and that persons who previously submitted data and comments may wish to reevaluate them in light of the reproposed tentative final monograph. Accordingly, the agency stated that data and comments submitted in response to the reproposal as well as data and comments submitted in response to the tentative final monograph published in the Federal Register of September 3, 1982 (47 FR 39102), would be considered by the agency in establishing a final monograph. Interested persons were invited to file by May 26, 1987, written comments, objections, or requests for oral hearing before the Commissioner of Food and Drugs regarding the reproposal. Interested persons were invited to file comments on the agency's economic impact determination by July 27, 1987. New data could have been submitted until March 27, 1988, and comments on the new data until May 27, 1988. Final agency action occurs with the publication of this final monograph, which is a final rule establishing a monograph for OTC wart remover drug products. All data and comments described above are being addressed in this document.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA is no longer using the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but is using instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III).

As discussed in the proposed regulation for OTC wart remover (52 FR 9992) drug products, the agency advised that the conditions under which the drug products that are subject to this monograph will be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication in the Federal Register. Therefore, on or after August 14, 1991, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

In response to the proposed rule on OTC wart remover drug products, four manufacturers and one medical professional submitted comments. No requests for oral hearing before the Commissioner were received. Copies of the comments received are on public display in the Dockets Management Branch. Any additional information that has come to the agency's attention since publication of the proposed rule is also on public display in the Dockets Management Branch (address above).

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices in the Federal Register of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the notice of proposed rulemaking. The volumes are on public

display in the Dockets Management Branch.

I. the Agency's Conclusions on the Comments

1. One comment applauded the reproposal of the tentative final monograph for its clarity, brevity, correctness, and the simple and reasonable definition for a "collodion-like" vehicle. The comment stated that clarification of this definition has been long needed. The comment concluded by saying that the proposed monograph in its present form is a paradigm of clear-thinking and careful rulemaking one likes to see coming from FDA.

2. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the Federal Register of May 11, 1972 (37 FR 9464); in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the Federal Register of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. (See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 696–98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), *aff'd*, 637 F.2d 887 (2d Cir. 1981).)

3. One comment expressed pleasure that the agency had expanded the concentration range and dosage form for salicylic acid to 12 to 40 percent in a plaster vehicle. Another comment supported the agency's Category I classification of salicylic acid at a 15-percent concentration in a plaster or collodion-like vehicle.

4. One comment stated that there were rumors that the combination of 16.7 percent salicylic acid and 16.7 percent lactic acid would be approved as a wart remover product for OTC human use. The comment contended that this would be a serious error because the potency of such a combination makes it necessary to restrict it to prescription use only.

After reviewing two studies that involved a combination product containing salicylic acid 16.7 percent and lactic acid 16.7 percent in flexible collodion and a third study that involved a combination product containing salicylic acid 5 percent and lactic acid 5 percent in flexible collodion, the Panel concluded that the lactic acid does not contribute greatly to the effectiveness of the combination and that salicylic acid is the active keratolytic ingredient (45 FR 65609 at 65617). The Miscellaneous External Panel placed this combination in Category III for effectiveness and concluded that data were needed to demonstrate that lactic acid contributes to the increased effectiveness of the combination over that of salicylic acid alone.

The agency agreed with the Panel's conclusions in the tentative final monograph for OTC wart remover drug products (47 FR 39102 at 39103). Following publication of that document on September 3, 1982, no additional data were received to support the combination of salicylic acid 5 to 17 percent and lactic acid 5 to 17 percent. Therefore, this combination is not included in the final monograph. (See also comment 8 below.)

5. One comment supported the reproposed tentative final monograph classification of 15 percent salicylic acid in a plaster or collodion-like vehicle as a Category I wart remover ingredient. The comment stated that its product, which contains 15 percent salicylic acid in a hydroscopic karaya gum pad with polypropylene backing, appears to comply with the reproposed monograph and should be marketable without new drug application (NDA) clearance. The product's labeling described the adhesive pad as being composed of natural nonsensitizing karaya, polyethylene glycol-300 U.S.P., propylene glycol U.S.P. and quaternium-15 and called the product a transdermal deliver system (Ref. 1).

The agency agrees that this product meets the definition of a plaster vehicle in § 358.103(c) of this final rule but finds that the product is not a transdermal delivery system. Transdermal delivery systems, such as those used to administer scopolamine, clonidine, estradiol, or nitroglycerin, are applied to the skin and the drug is absorbed continuously through the skin into the systematic circulation to provide therapeutic serum levels (Ref. 2). The comment's own labeling statements (e.g., the delivery systems provides for a more steady release of the drug into the stratum corneum, and the drug's activity appears to be due to a keratolytic action which results in mechanical removal of stratum corneum cells infected with the papilloma virus) argue against a transdermal designation because systemic absorption does not occur and the clinical effect is not a systemic one. The pharmacological activity results from a keratolytic action that leads to mechanical removal of stratum corneum cells infected with the papilloma virus in the same manner as other products subject to this rulemaking. After this comment was submitted, the company was informed (in a pending NDA for this product) that the reference to a transdermal wart removal system should not be included in the product's labeling (Ref. 3). Accordingly, it is not necessary to proceed with approval of the NDA. However, in order to be marketed OTC in accordance with this final monograph, the product must comply with these labeling provisions and not be labeled a transdermal delivery system. (See comment 13 below, for additional discussion of labeling.)

References

(1) Comment No. C00007, Docket No. 80N–0238, Dockets Management Branch.

(2) "Physicians' Desk Reference," 44th Edition, Medical Economics Company, Inc., Oradell, NJ, pp. 685–686, 853–856, 2042, 2070–2071, and 2181–2182, 1990.

(3) Letter from E. Tabor, FDA, to J. Neveaux, Minnetonka, Inc., dated March 7, 1988, included in OTC Volume 16CFM, Docket No. 80N–0238, Dockets Management Branch.

6. One comment asked about the future of a product containing 17 percent salicylic acid in a collodion-like vehicle that it claimed fits the definition of an OTC wart remover but is currently being marketed as a prescription product. Contending that advertisements for the product strongly suggest that it contains lactic acid as well as salicylic acid, the comment stated that marketing of this product has been particularly confusing for physicians.

The agency is aware that the product referred to by the comment is currently being marketed as a prescription product. However, there is no indication from the current or previous labeling (Refs. 1, 2, and 3) that this product also contains lactic acid. The agency is not aware of any advertisements that state or strongly suggest that the product contains lactic acid, and the comment did not provide any examples of advertisements to support its contention. The agency also is not aware that this product's marketing has been particularly confusing to physicians, and the comment did not provide any evidence to support its position.

Similar products can be marketed both prescription and OTC before a final monograph becomes effective. The agency will examine the labeling of this

product when the monograph becomes effective and determine the product's status at that point as part of normal compliance activity following establishment of a final monograph. Any necessary regulatory action will be considered at that time.

References

(1) "Physicians' Desk Reference," 44th Ed., Medical Economics Co., Inc., Oradell, NJ, pp. 998–999, 1990.

(2) "Physicians' Desk Reference," 43d Ed., Medical Economics Co., Inc., Oradell, NJ, p. 986, 1989.

(3) "Physicians' Desk Reference," 42d Ed., Medical Economics Co., Inc., Oradell, NJ, p. 907, 1988.

7. One manufacturer submitted new data on 17 percent salicylic acid in what it described as a polyacrylic film vehicle. The data are from a multi-center, double-blind, controlled clinical trial to evaluate the safety and effectiveness of 17 percent salicylic acid in this polyacrylic film vehicle versus the polyacrylic film vehicle without the active ingredient (Ref. 1). Subsequently, the manufacturer submitted additional information stating that the polyacrylic vehicle is already classified in Category I in the tentative final monograph (Ref. 2). The manufacturer explained that its vehicle contained pyroxylin (nitrocellulose), volatile solvents (alcohol and toluene), and a plasticizer (acrylates copolymer), and the vehicle meets the description of flexible collodion contained in the Miscellaneous External Panel's report (45 FR 65609 at 65612). The manufacturer added that all ingredients but one (polyester resin) are listed in the Cosmetic, Toiletry and Fragrance Association's Cosmetic Ingredient Dictionary, and that polyester resin is composed of trimellitic anhydride, adipic acid, neopentyl glycol, and cyclohexane dimethanol 70 percent in normal butyl acetate. The manufacturer also stated that polyester resin is a component of a number of widely used commercially available nail polishes (Ref. 3).

Subsequently, additional data were obtained for a total of 62 subjects, of which 59 were acceptable for efficacy evaluation (Refs. 1 and 4). Subjects were divided on a random basis to either the active treatment group (30 subjects) or the vehicle treatment group (29 subjects). Treatments were blinded to both the subjects and investigators. The subjects were instructed to soak each wart with warm water for at least 5 minutes, to dry the area thoroughly, and then paint the surface of the wart. Subjects were advised to discontinue use if excessive irritation occurred. At the initial visit, a description of each wart's location, size, and thickness was made. At each follow-up visit (weeks 2 and 3), the size and thickness of each wart were determined and compared to baseline values. Additionally, at each follow-up visit, each wart's response to medication was assessed as cured, resolving, same (failures), or worse. For the 30 subjects who received active drug treatment for 3 weeks, 9 (30 percent) were rated as cured, 12 (40 percent) were rated as resolving, 9 (30 percent) were rated as same, and 0 were rated as worse. For the 29 subjects who received placebo for 3 weeks, 1 (3 percent) was rated as cured, 4 (14 percent) were rated as resolving, 23 (79 percent) was rated as same, and 1 (3 percent) was rated as worse. Differences in mean wart areas from baseline to week 3 were not statistically significant, but differences in mean wart thicknesses was statistically signficant for the active medication group ($p < 0.01$).

None of the subjects experienced an adverse reaction severe enough to be taken out of the study. Only 3 adverse reactions were reported—all in the active medication group. One subject manifested red and raw areas of a mild degree surrounding treated warts, which lasted for 2 days. Another subject was being treated for five warts, one of which kept breaking open during therapy and manifested a moderate amount of bleeding for 3 to 4 days. The investigator reported that this reaction had an unknown etiology, but discontinued treating that one wart. The third subject complained of a mild burning and itching in interdigital areas for about 15 minutes during 1 day of treatment. Etiology was unknown and study medication was continued.

The agency has evaluated the manufacturer's vehicle described above and determined that it meets the definition of a "collodion-like vehicle" included in § 358.103(b) of this final monograph. The Panel designated collodion as the vehicle for liquid wart remover drug products containing salicylic acid (45 FR 65609 at 65618). Collodion is an official article in the United States Pharmacopeia (U.S.P.) (Ref. 5). The Panel noted that salicylic acid used in the treatment of warts is usually formulated in flexible collodion, which contains pyroxylin (a nitrocellulose derivative), volatile solvents (ether, acetone, or alcohol), and plasticizers (camphor and castor oil) (45 FR 65612). Flexible collodion is also an official article in the U.S.P. (Ref. 5).

In the tentative final monograph for OTC corn and callus remover drug products, the agency noted that, in addition to collodion and flexible collodion, some formulations contain other inactive ingredients or varying amounts of solvent which provide for increased spreadability and increased pliability of the product after it dries on the skin (52 FR 5412 at 5414). The agency proposed the term "collodion-like" instead of "collodion" in specifying the vehicle for liquid formulations containing salicylic acid and defined "collodion-like" as follows: "A solution containing pyroxylin (nitrocellulose) in an appropriate nonaqueous solvent that leaves a transparent cohesive film when applied to the skin in a thin layer." The agency also proposed this same definition for salicylic acid used in liquid formulations as OTC wart remover drug products (52 FR 9992 at 9993).

The manufacturer's vehicle in the salicylic acid product used in the clinical trial described above contains pyroxylin (nitrocellulose) in a nonaqueous solvent that leaves a transparent cohensive film when applied to the skin. The vehicle also contains a plasticizer as does flexible collodion. The agency has determined that the clinical trial described above shows that salicylic acid in this vehicle is effective and the vehilce does not cause adverse reactions that would cause it to be considered unsafe. Further, the vehicle is a common nail polish formulation (Refs. 3 and 6), which the agency considers to be safe. Thus, the agency concludes that 17 percent salicylic acid in the manufacturer's vehicle is generally recognized as safe and effective as an OTC wart remover drug product when labeled according to the conditions of this final monograph.

References

(1) Comment No. RPT, Docket No. 80N–0238, Dockets Management Branch.

(2) Comment No. C00003, Docket No. 80N–0238, Dockets Management Branch.

(3) Formulation for Nail Polish Tevco Vehicle #32403, identified as Exhibit #25d, February 28, 1985, included in OTC Volume 16CFM, Docket No. 80N–0238, Dockets Management Branch.

(4) "Supplemental Efficacy Data for Study 83–07" identified as Exhibit #21, dated February 28, 1985, included in OTC Volume 16CFM, Docket No. 80N–0238, Dockets Management Branch.

(5) "United States Pharmacopeia XXII—National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 353, 1989.

(6) Memorandum of Telephone Conversation between K. Freeman, FDA, and J. Wenninger, FDA, is included in OTC Volume 16CFM, Docket No. 80N–0238, Dockets Management Branch.

8. One comment requested that lactic acid be considered an inactive

ingredient rather than as an active ingredient in OTC wart remover drug products. The comment asked that § 358.110 of the tentative final monograph be rewritten to include the phrase "or in a lactic acid collodion vehicle" as follows: "The active ingredient and its concentration in the product is as follows: salicylic acid 5 to 17 percent in a collodion vehicle or in a lactic acid collodion vehicle." Alternatively, the comment requested that the phrase "in a collodion vehicle" not be included in § 358.110 of the final monograph.

The comment contended that "lactic acid (5 to 17 percent) when added to salicylic acid (5 to 17 percent) in a collodion base results in a drug formulation of better quality than the same formulation without the salicylic acid." The comment explained that a topical collodion vehicle containing a therapeutically active ingredient must have three primary characteristics: (1) Act as a protective agent to the drug, (2) adhere to the skin after its solvent has evaporated, and (3) retain a residual nonvolatile liquid content sufficient to enable the active ingredient to retain enough solubility to permit molecular transfer into the skin. The comment further explained that when salicylic acid alone is dissolved in flexible collodion and applied to the skin, a dry film is created as a result of evaporation, causing poor adhesion of the salicylic acid as well as inefficient drug mobility. The comment stated that it has found that including 15 to 20 percent lactic acid in the product will overcome these deficiencies because lactic acid satisfies the following criteria: (1) Its oil/water solubility characteristics permit improved adhesion of the drug to the skin, and (2) lactic acid does not evaporate from the film. The comment also stated that the solubility of salicylic acid in lactic acid is 3 percent, so that the lactic acid remains saturated with salicylic acid throughout the treatment period, with sufficient solubility for efficient molecular transfer into the skin.

In further support of lactic acid's enhancement of adhesion of salicylic acid in collodion, the comment cited an unpublished in-vitro study carried out with salicylic acid collodion preparations containing 18.7 percent salicylic acid and varying amounts of lactic acid in order to demonstrate the concentration of lactic acid which would be most beneficial to the finished product (Ref. 1). Based on visual evaluation of adhesion properties, 15 percent lactic acid provided the best adhesive characteristics with a coherent film on the walls of the glass tubes. Concentrations of lactic acid ranging from 0 to 10 percent and from 20 to 25 percent were rated for adhesion as either nil or slight (Ref. 1).

The comment stated that its product contains salicylic acid and lactic acid 16.7 percent each, and flexible collodion 66.6 percent in order to obtain a 1:1:4 weight-to-weight ratio of the acids in the flexible collodion. The comment asserted that lactic acid's safety has been clearly established, citing the Miscellaneous External Panel's report (45 FR 65609 at 65615; October 3, 1980) and the tentative final monograph on OTC wart remover drug products (47 FR 39102 at 39103; September 3, 1982) as support.

The comment stated that the use of lactic acid as an inactive ingredient is in accord with 21 CFR 330.1(e), which provides that monograph products may contain only those suitable inactive ingredients which are safe in the amounts administered and which do not interfere with the preparation's effectiveness or with suitable tests or assays to determine if a drug meets its professed standards. The comment mentioned that salicylic and lactic acids can be quantified separately in the same formulation; thus, there is no interaction between them. The comment added that the Panel concluded from the Bunney study (Ref. 2) that salicylic acid rather than lactic acid is responsible for effectiveness and that lactic acid is not interfering with the salicylic acid when enhancing the formulation's pharmaceutical qualities (45 FR 65609 at 65617).

The comment further contended that neither the Panel nor FDA considered whether lactic acid was a suitable inactive ingredient in wart removal drug products and that there was no reason to do so because the OTC drug review is concerned almost exclusively with active ingredients. The comment noted that lactic acid was reviewed as an active ingredient.

The comment cited as precedent an agency letter (Ref. 3) notifying another manufacturer that oil of turpentine could be included as an inactive ingredient for organoleptic reasons in an antitussive drug product when oil of turpentine had been classified in Category III as an antitussive active ingredient.

The comment contended that if the tentative final monograph for OTC wart remover drug products had not specified the inactive ingredient, i.e., in a collodion vehicle, for wart remover drug products, lactic acid could have been included as an inactive ingredient in a wart removal drug product without the necessity of obtaining a modification of the monograph. The comment claimed that the tentative final monograph as presently written would permit the inclusion of lactic acid along with the collodion as a suitable inactive ingredient pursuant to 21 CFR 330.1(e). However, in order to remove any ambiguity with regard to the issue, the comment urged that the tentative final monograph be amended to include lactic acid as an inactive ingredient or, in the alternative, that no inactive ingredients be specified.

The agency disagrees with the comment's requests. The Panel reviewed lactic acid as an active ingredient in OTC wart remover drug products (45 FR 65609 at 65615). The comment's statement about the Panel's conclusions from the Bunney study (Ref. 2) is out of context. The Panel stated it could find no data on the use of lactic acid alone in the treatment of warts, and that data showing that lactic acid contributes to the increased effectiveness of the combination over that of salicylic acid alone are needed to upgrade the combination to Category I (45 FR 65617). When the Panel concluded that lactic acid does not contribute greatly to the combination's effectiveness, it did not regard lactic acid as an inactive ingredient but as an ingredient for which no data were found to support its use as a wart remover.

The Panel mentioned a study by Van Scott and Yu (Ref. 4), which stated that lactic acid is one of a group of compounds that modify keratinization in ichthyosis. Histologically, preparations of biopsy specimens taken from treated and untreated skin reveal distinct changes that suggest that these compounds may cause an immediate effect on epidermis keratinization. One change that occurs is abrupt loss of the entire stratum corneum. This is seen clinically by sudden separation of thick scales to reveal a normal skin surface. Another change noted in this study is that significant shedding occurs, reducing the thickness of the epidermis (45 FR 65610). These microscopic and clinical changes attributable to lactic acid clearly fall within the statutory definition of the effects produced by a drug. The act defines a "drug" in part as an article "intended to affect the structure or function of the body" (21 U.S.C. 321(g)(1)(C)). Another submission (Ref. 5) supporting the use of 5 percent lactic acid in combination with salicylic acid described lactic acid as being a caustic agent, having keratoylic activity, and as having corrosive properties. The study by Van Scott and Yu and the submission (Ref. 5) clearly indicate that

lactic acid is an active ingredient, i.e., a drug, when used in these types of products.

The comment presently markets a prescription wart remover drug product containing salicylic acid 16.7 percent and lactic acid 16.7 percent as active ingredients in a collodion vehicle (Ref. 6). Product labeling states that its pharmacologic activity is generally attributed to the keratolytic action of both lactic acid and salicylic acid (Ref. 6). Another company also markets a product containing the same active ingredients in the same concentration with the same labeling statement of pharmacologic activity (Ref. 7). Lactic acid 16.7 percent cannot be an inactive OTC ingredient and also be an active ingredient at the same concentration in similar products.

The agency regards lactic acid to be an active ingredient in products labeled for the removal of warts and is not including lactic acid in the final monograph as an optional inactive ingredient as suggested by the comment because of a lack of data demonstrating its effectiveness. Further, in a proposed rule on inactive ingredients (April 12, 1977; 42 FR 19156 at 19157), the agency stated the following:

> Various OTC drug panels have questioned whether an OTC drug may retain as an inactive ingredient an ingredient that was formerly listed as an active ingredient, but which was found not to be generally recognized as safe and effective (Category II) or to require additional testing (Category III). If these ingredients have been promoted by manufacturers for an extended time, there is a potential for misleading consumers if the general recognition of the safety and effectiveness issue is unresolved and the name of the ingredient is retained on the label or in the labeling with an unwarranted degree of prominence. The Commissioner believes this should not be permitted, and this proposal is intended to preclude the retention and redesignation of an active ingredient as an inactive ingredient unless it serves an acceptable function as an inactive ingredient. As a result, manufacturers of OTC drug products containing an ingredient in Category II or Category III shall, at the end of the time period permitted for marketing, or if found to require further testing before a determination as to general recognition of safety and effectiveness can be made for such ingredients, be required by the effective date either to reformulate the product to remove the ingredient or if it is retained in the product as an inactive ingredient, to establish that the ingredient fulfills the requirements for use as an inactive ingredient in the product.

If lactic acid is retained in a wart remover drug product as an inactive ingredient, the manufacturer must establish that lactic acid fulfills the requirements for use as an inactive ingredient. The intended uses of lactic acid, as the comment stated, are as a protective agent to the drug, as an adherent to the skin after the solvent has evaporated, and as a retentive of residual nonvolatile liquid sufficient to retain enough solubility to permit molecular transfer into the skin. The physical characteristic of adhesion of various concentrations of lactic acid is reported in the comment's description of an unpublished in-vitro study's results (Ref. 1). The agency cannot use the comment's description of the study as the sole basis to determine the inactive ingredient status of lactic acid nor can the agency ignore the keratolytic activity of lactic acid, as noted above. Despite the comment's contention that lactic acid is a protective and adherent, lactic acid is still an active ingredient that has not been shown to produce an effective level of keratolysis sufficient to be included in this final monograph. Furthermore, the agency's proposed rule on inactive ingredients lists a number of uses of inactive ingredients (42 FR 19156 at 19160). It does not include the protective and adherent uses of lactic acid as the comment described. It does include under proposed § 330.3(p) "solvents and vehicles": "Substances used to dissolve or extract another substance or used as carriers of other substances." However, the agency considers that mechanism as being different from retaining a residual nonvolatile liquid, as mentioned by the comment. Therefore, the agency does not consider lactic acid an inactive ingredient for any use listed in its proposal at 42 FR 19160.

With regard to the comment's argument about the dual status of oil of turpentine, data were submitted to the Cough-Cold Panel on the use of oil of turpentine as an active antitussive ingredient combined with menthol, camphor, eucalyptus oil, thymol, and myristica oil in a petrolatum ointment base for application to the chest. Based on submitted data, in the final monograph for OTC antitussive drug products (52 FR 30042 at 30054; August 12, 1987), the agency made a final determination that oil of turpentine was a nonmonograph active ingredient. Publication of the final monograph superseded the agency's letter of February 16, 1983 (Ref. 3) discussing oil of turpentine. In addition, in the tentative final monograph on cough, cold, allergy, bronchodilator, and antiasthmatic combination drug products (53 FR 30522 at 30547: August 12, 1988), the agency determined that oil of turpentine at 4.5 percent was an active ingredient but classified thymol 0.1 percent, cedarleaf oil 0.38 percent, and myristica oil 0.485 percent as inactive ingredients because of their low concentrations. Menthol 2.6 percent, camphor 4.7 percent, and eucalyptus oil 1.2 percent, were considered active ingredients (53 FR 30547). Although oil of turpentine in a combination is still pending further proceedings in the cough-cold combinations rulemaking, the agency considers the status of oil of turpentine an active ingredient, and the agency's position on that ingredient does not support the comment's argument that lactic acid is an inactive ingredient.

For the reasons stated above, the agency is classifying lactic acid (5 to 17 percent) a nonmonograph active ingredient in this final rule.

References

(1) Comment No. C00002, description of unpublished in-vitro study by Dermal Laboratories, Ltd., pp. 3–4, Docket No. 80N–0238, Dockets Management Branch.

(2) Bunney, M.H., M.W. Nolan, and D.A. Williams. "An Assessment of Methods of Treating Viral Warts by Comparative Treatment Trials Based on a Standard Design," British Journal of Dermatology, 94:667–679, 1976.

(3) Letter from W.E. Gilbertson, FDA to G.F. Hoffnagle, Richardson-Vicks, Inc., coded ANS 1, Docket No. 76N–052T, Dockets Management Branch.

(4) Van Scott, E.J., and R.J. Yu, "Control and Keratinization with a-Hydroxy Acids and Related Compounds. Topical Treatment of Ichthyotic Disorders." Archives of Dermatology, 110:586–590, 1974.

(5) OTC Volume 160359, pp. 5, 59, and 60.

(6) "Physicians' Desk Reference," 43d Ed., Medical Economics Co., Inc., Oradell, NJ, p. 621, 1989.

(7) "Physicians' Desk Reference," 44th Ed., Medical Economics Co., Inc., Oradell, NJ, p. 2163, 1990.

9. One comment urged the agency to consider requiring a package insert for OTC wart remover drug products that would clearly describe, in layman's terms, the type of warts on which the drug could be used, a simple explanation of how the drug works, how it should be used, the potential side effects, and the precautions and contraindications, especially for the elderly. The comment did not feel that the labeling proposed in § 358.150 was sufficient for the lay population to safely and effectively self-medicate with these products. Noting that salicylic acid is "not without side effects or risks," the comment was specifically concerned about risks in the elderly population because of the higher incidence of diabetes mellitus, peripheral vascular disease, and decreased visual acuity.

The agency appreciates the comment's concern, but does not believe

that it is necessary to require a package insert for OTC wart remover drug products. The agency is aware that the Miscellaneous External Panel considered self-medication by the elderly with OTC wart remover drug products and, accordingly, proposed certain warnings, which the agency has adopted. These warnings address several of the concerns raised by the comment. The Panel recommended the following warning "Do not use if you are a diabetic or have poor blood circulation because serious complications may result." (See 45 FR 65609 at 65618.) The agency concurred with this recommendation in the tentative final monograph 47 FR 39102 at 39104 and in the reproposed tentative final monograph (52 FR 9992 at 9993). However, in this document the warning has been revised and is included in § 358.150(c)(1)(ii) of this final monograph. See comment 11 below.

The Panel noted that systemic absorption of salicylates occurs whether the salicylates are administered orally, rectally, intravenously, or cutaneously (through the skin) (45 FR 65609 at 65612). However, the Panel stated that it was unaware of any report of salicylism (toxic reaction) occurring from the cutaneous use of salicylic acid as a wart remover. The agency also is not aware of any such reports. Therefore, the agency concludes that the labeling information required by § 358.150 of this final monograph should provide for the safe and effective use of OTC wart remover drug products by all populations, including the elderly.

The agency is aware that wart remover drug products are marketed in small containers and that it is difficult to print all of the required labeling information on the immediate container label in a print size that can readily be read by elderly consumers. The agency encourages manufacturers of these products to provide a consumer package insert or outer container that provides a larger size print for all consumers, particularly for the elderly. The agency has no objection if manufacturers provide additional information of the type requested by the comment in addition to the required monograph labeling. Manufacturers are also encouraged to print a statement on the product container label, carton, or package insert suggesting that the consumer retain the carton or package insert for complete information about the use of the product when all the required labeling does not appear on the product container label.

10. One comment recommended that the definition of "collodion-like vehicle" in proposed § 358.103 be slightly modified to read as follows: "A solution containing pyroxylin or film-forming vehicle in an appropriate solvent that leaves a transparent cohesive film when applied to the skin in a thin layer." The comment contended that this proposed definition would clarify that "any appropriate vehicle similar to a collodion (*e.g.*, collodion-like) would be acceptable," and that this flexibility of choice of vehicles allows for scientific improvement and refinement beyond the vehicles commonly used today, without necessitating amendment of a final monograph. The comment added that its request comports with the agency's rationale for expanding the definition from "collodion" to "collodion-like" (52 FR 9992 at 9993) and is consistent with the broad definition the agency gave to "plaster vehicle," which allows for improved topical patches utilizing technologies beyond those specifically in use today.

While the agency has tried to be flexible in the monograph definitions to allow for reasonable product improvement and innovation, it does not agree with the comment's proposed modification of the definition of a collodion-like vehicle. Addition of the words "film-forming vehicle" in the definition would make the definition too broad, would expand the definition beyond vehicles that are similar to collodion, and could allow any "film-forming vehicle" to be used. If this occurred, it could result in the introduction into the market of a wide variety of natural and synthetic film-forming compounds whose impact on the safety and effectiveness of salicylic acid is unproven. It is possible that such compounds could eventually be included in the final monograph, but data would be needed to support their interaction with salicylic acid used in wart remover drug products. Accordingly, the agency is not revising the definition of "collodion-like vehicle" in § 358.103 at this time, but will consider doing so in the future if vehicles of the type requested by the comment are found to be acceptable for inclusion in the monograph.

11. One comment suggested "a slight variation" to the warning proposed in § 358.150(c)(1)(ii), to read as follows: "Do not use if you are diabetic or have poor circulation or if there is any inflammation or irritation of the affected area." The comment stated that this proposed revision is preferable because it combines the warnings in § 358.150(c)(1) (ii) and (iii) and is stronger in its exhortation against use by diabetics and those with poor circulation. The comment contended that advising diabetics against the use of salicylic acid is medically sound and standard physician practice. The comment concluded that, for medical and product liability reasons, it would prefer to retain its label warning (suggested above) that it has used in recent years on its wart remover drug products. The comment did not include any documentation in support of the more stringent, combined warning.

The agency notes that the comment's suggestion involves more than the combining of two warnings. The warning against use by diabetics that the agency proposed in the tentative final monograph reads as follows: "Do not use this product if you are a diabetic or have poor blood circulation, except under the advice and supervision of a doctor." The other warning proposed by the agency in the tentative final monograph reads as follows: "Do not use on irritated skin or on any area that is infected or reddened." The first warning to "diabetics" allows use of the product under a doctor's supervision. The second warning describes a "do not use" condition and is not dependent on advice or supervision by a doctor. The warning suggested by the comment would eliminate use of the product by a diabetic even under a doctor's supervision.

The Panel, in its review of keratolytics (chemical agents used to treat warts), considered the safety issues concerning the use of salicylic acid by diabetics and those individuals having poor blood circulation. After reviewing the data available at that time, and considering its members' experience, the Panel stated (45 FR 65609 at 65611):

> However, persons with poor circulation or diabetes should not use OTC preparations for removing warts except on the advice and under the supervision of a doctor. The Panel feels that such individuals are more prone to infections which may result from injury to surrounding skin by the OTC preparation or by mechanical attempts to remove the wart.

In evaluating the comment's suggestion, the agency reviewed a number of commonly used reference books (Refs. 1 through 4) but found that the references do not support the comment's contention that diabetics and individuals with poor circulation absolutely should not use wart remover drug products. For example, Basic & Clinical Pharmacology mentions that "Particular care must be exercised when using the drug on the extremities of diabetics or patients with peripheral vascular disease," (Ref. 1). Drug Evaluations (Ref. 2) states that caution must be exercised when a 40-percent

plaster is used, particularly on the extremities, in diabetics, or in patients with peripheral vascular disease, "since acute inflammation and ulceration may occur after excessive use." The United States Dispensatory (Ref. 3) states that plasters containing 40 percent of salicylic acid may cause acute inflammation and ulceration in diabetics or in persons with peripheral vascular disease "if not used with caution." Drug Information for the Health Care Provider (Ref. 4), in its discussion of the topical use of salicylic acid, states that products containing 25 percent or more of salicylic acid are not recommended for use on inflamed skin * * * or in individuals with diabetes or circulatory failure (impairment) since acute inflammation or ulceration may occur.

In discussing factors that lead to tissue necrosis in the diabetic foot, Edmonds (Ref. 5) states that "chemical trauma can result from the use of keratolytic agents such as 'corn plasters.' They often contain salicylic acid which causes ulceration in the diabetic foot." In providing general advice on foot care for the "at risk" diabetic patient, Boulton (Ref. 6) states "Do not use chemical agents (keratolytics) to treat calluses or corns."

The agency also reviewed the labeling for keratolytic drug products containing salicylic acid that appears in the Physician's Desk Reference for Nonprescription Drugs (Ref. 7) and found that the labeling for the listed wart remover drug products contain a warning that the product is not recommended for use by diabetics or individuals with impaired or poor blood circulation.

Based on the above, the agency has determined that there is adequate support for a stronger warning, as requested by the comment. In addition, based on the serious consequences that can result from misuse, the agency believes it is better to err on the side of caution and to have the labeling of these OTC drug products state that the product should not be used under certain conditions rather than state an "except under" condition for use. Therefore, the agency is agreeing with the comment's suggested approach to combine the warnings in § 358.150(c) (ii) and (iii) but is revising its recommended warning slightly for clarity. The revised warning appears in § 358.150(c)(1)(ii) of this final monograph as follows: "Do not use this product on irritated skin, on any area that is infected or reddened, if you are a diabetic, or if you have poor blood circulation." This revised warning now contains the same information as the warning proposed in § 358.150(c)(i)(iii), and that warning is not included in this final monograph. Accordingly, the warnings in paragraphs (c)(1) (iv) and (v) are redesignated as (iii) and (iv) in this final monograph.

References

(1) Katzung, B.G., editor, "Dermatologic Pharmacology," in "Basic & Clinical Pharmacology," 2d Ed., Lange Medical Publications, Los Altos, CA, p. 768, 1984.

(2) "Antiviral Agents for Warts and Molluscum Contagiosum," in "Drug Evaluations," 6th Ed., American Medical Association, Chicago, p. 1518, 1986.

(3) Osol, A., R. Pratt, and A.R. Gennaro, "The United States Dispensatory," 27th Ed., J.B. Lippincott Co., Philadelphia, p. 1035, 1973.

(4) "Salicyclic Acid (Topical)," in "Drug Information for the Health Care Provider", 5th Ed., Mack Printing Co., Easton, PA, p. 1121, 1985.

(5) Edmonds, M.E., "The Diabetic Foot: Pathophysiology and Treatment," Clinics in Endocrinology and Metabolism, 15:897, 1986.

(6) Boulton, A.J.M., "The Diabetic Foot," The Medical Clinics of North America, 72:1520, 1988.

(7) "Physician's Desk Reference for Nonprescription Drugs," 11th Ed., Medical Economics Co., Inc., Oradell, NJ, pp. 587 and 747, 1990.

12. One comment stated that the directions for use of most currently marketed wart remover drug products containing salicylic acid suggest that the user soak the area before application of the product. Noting that it has no data that soaking is mandatory, the comment requested that "permissive soaking" be allowed in the directions and suggested the following language be included in § 358.150(d):

(1) *For products containing salicylic acid identified in § 358.110(a).* "Wash affected area (soaking wart for several minutes, if desired) before drying thoroughly." (If appropriate: "Cut plaster to fit wart.") "Apply medicated plaster. Repeat procedure every 48 hours as needed (until wart is removed) for up to 12 weeks."

(2) *For products containing salicylic acid identified in § 358.110(b).* "Wash affected area (soaking wart for several minutes, if desired) before drying thoroughly." Apply one drop at a time to sufficiently cover each wart. Let dry. Repeat this procedure once or twice daily as needed (until wart is removed) for up to 12 weeks."

Another comment addressed the directions included in § 358.150(d) of the first tentative final monograph on OTC wart remover drug products (47 FR 39102 at 39104 to 39105). These directions included soaking the wart for 5 minutes before applying the salicylic acid product. The comment contended that this procedure is unnecessary because any product containing salicylic acid as a keratolytic would be effective without soaking. The comment requested that the sentence "Wash affected area and soak wart for 5 minutes" be deleted from the directions.

The agency has reviewed the Panel's discussion of wart remover drug products and notes that the Panel stated that "the therapeutic effectiveness of salicylic acid in wart therapy depends upon the presence of moisture; therefore, salicylic acid is usually incorporated into vehicles (plasters, flexible collodions, occlusive ointments) that occlude the area and promote hydration (taking up of water), causing maceration of the skin" (45 FR 65609 at 65612). Although the Panel did not discuss whether test subjects did or did not soak the affected area before applying the wart remover product containing salicylic acid , it did include soaking of the wart for 5 minutes before application of the product as part of its recommended directions (45 FR 65609 at 65613).

In the tentative final monograph for OTC corn and callus remover drug products, published in the Federal Register of February 20, 1987 (52 FR 5412), the agency reviewed the results of a double-blind placebo-controlled study in which the effect of soaking as a means of increasing efficacy of salicylic acid in removing soft corns was evaluated (Ref. 1). At that time, the agency determined that it was unnecessary to soak the affected area and revised the previously-proposed directions to eliminate "soaking" (52 FR 5416). The agency has re-evaluated this study and determined that it did not include a "non-soaking" group, but that all test subjects soaked the corn for 5 minutes before applying the medication and soaked for either 5 minutes or 15 minutes before attempting removal of the corn. Although this study did not show that soaking 5 minutes prior to applying the salicylic acid is necessary for salicylic acid to be effective, it also did not show that any adverse effects occur if the corn is soaked before the area is dried and the corn remover product applied. The agency notes that although this study was conducted on soft corns, the same findings are relevant to the removal of hard corns/calluses and warts because the category I active ingredient, salicylic acid, and its mode of action, keratolysis, are the same for all three conditions. It is possible that soaking increases the presence of moisture in the corn or wart, which then may promote hydration and aid the therapeutic effectiveness of salicylic acid, as the Panel indicated.

The agency has examined the directions for use for a number of currently marketed wart remover drug products and notes that some include soaking the wart for varied periods of time ranging from several minutes up to 30 minutes before the product is applied. Some of the products include directions to soak in hot water and some say to use warm water, while others do not specify temperature (Refs. 2 and 3).

There is no evidence that using different soaking times or temperatures is likely to alter the effectiveness of the wart remover drug products. The agency believes that while hot water may cause burns, warm or cold water could be used effectively for soaking but that warm water would be more comfortable. Based on the panel's recommendation, the agency's re-evaluation of the study discussed above, and on the historical and current use of wart remover drug products, the agency is including soaking of the wart in warm water for 5 minutes before application of the salicylic acid as an optional direction for those manufacturers who wish to give consumers the option to do so. Accordingly, the agency is revising § 358.150(d) in this final monograph to read as follows:

(1) *For products containing salicylic acid identified in § 358.110(a).* "Wash affected area." (optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly." (If appropriate: "Cut plaster to fit wart.") "Apply medicated plaster. Repeat procedure every 48 hours as needed (until wart is removed) for up to 12 weeks."

(2) *For products containing salicylic acid identified in § 358.110(b).* "Wash affected area." (optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly. Apply one drop at a time to sufficiently cover each wart. Let dry. Repeat this procedure once or twice daily as needed (until wart is removed) for up to 12 weeks."

References

(1) Goodman, J.J., and L. Farris, "Evaluation of Safety and Effectiveness of 20% Salicylic Acid for the Removal of Soft Corns," (Scholl Study No. S–82–47), draft of unpublished study, Comment No. LET, Docket No. 81N–0122, Dockets Management Branch.

(2) "Physicians' Desk reference for Nonprescription drugs," 11th Ed., Medical Economics Co., Oradell, NJ, pp. 587 and 747, 1990.

(3) Labels for currently marketed wart remover drug products included in OTC Volume 16PFM, Docket No. 80N–0238, Dockets Management Branch.

13. One comment suggested three modifications to the directions proposed in § 358.150(d)(1) for wart remover drug products in a plaster vehicle to accommodate its salicylic acid product in an adhesive pad delivery system. (See comment 5 above.) The comment requested the following additions (italicized) to the proposed directions: "Wash affected area and dry thoroughly." (If appropriate: "Cut plaster *material* to fit wart.") "Apply medicated plaster *as directed.* Repeat procedure every *24 to 48* hours as needed (until wart is removed) for up to 12 weeks."

The agency notes that the definition of "plaster vehicle" in this final monograph refers to a "fabric, plastic, or other suitable backing material * * *." Accordingly, adding the word "material" after the word "plaster," as suggested by the comment, would provide no additional useful information to the user of the product.

The agency also does not see any benefit to adding the words "as directed," as suggested by the comment, because these OTC drug products are intended for self-diagnosis and treatment and are not dependent on the receipt of directions from a doctor. If there are any special directions that relate to using a particular product, then such information should appear as part of the manufacturer's additional directions for the product. The monograph provides the minimum directions necessary for use of the product. Manufacturers may supplement these directions with additional information necessary to use their specific product. For example, the agency notes that the manufacturer's directions for its specific product include statements to "keep plastic film on the top of pad facing up and to apply sticky bottom side to the wart." The agency finds no need to incude such directions in this final monograph; however, manufacturers may add such information, as appropriate, to the labeling of their products.

Neither the Miscellaneous External Panel's report (45 FR 65609) nor the first tentative final monograph for OTC wart remover drug products (47 FR 39102) included salicylic acid in a plaster vehicle. The directions for salicylic acid in a plaster vehicle that were included in the reproposed tentative final monograph for OTC wart remover drug products were based upon data and comments submitted to the rulemaking for OTC corn/callus remover drug products (52 FR 9992). In developing those directions, the agency recognized that, although the etiology and pathology of corns and calluses are different from that of warts, the Category I active ingredient, salicylic acid, and its mode of action, keratolysis, are common to both rulemakings (52 FR 9992). The studies that supported the effectiveness of 40 percent salicylic acid in a plaster vehicle for the treatment of corns and calluses utilized a 48-hour treatment interval (47 FR 526).

The comment submitted data from three double-blind, placebo controlled clinical studies (Ref. 1). The purpose of two of the studies was to investigate the efficacy of 5 percent and 15 percent concentrations of salicylic acid in the treatment of common warts when administered in a karaya gum, glycol patch. The control patch was a polymer of karaya gum plus glycols without the salicylic acid. The amount of the glycols was increased to compensate for the missing salicylic acid. The treatment period of the studies was 12 weeks, with dermatologist evaluation at weeks 2, 4, 6, 8, and 12. Subjects were directed to apply the patch at bedtime, to leave it on at least 8 hours, and remove and discard the patch in the morning. Treatments were repeated daily. The same protocol was used at studies at two sites; 66 subjects completed one study, and 52 subjects completed the other study. No subjects were dropped from either study because of adverse reactions. The agency concluded that only one of the studies showed superiority in both the number of subjects cured and the number of warts cured. The other study indicated that, for warts cured, the 15 percent concentration of salicylic acid was not statistically different from placebo. The third study evaluated only the 15 percent concentration of salicylic acid versus its karaya gum glycol placebo vehicle. A total of 61 subjects entered the study, but 8 were excluded from evaluation for compliance reasons. Subjects again applied the treatments for 8 hours at bedtime on a daily basis. Warts were evaluated at 4, 8, and 12 weeks. The data indicate that the product is superior to placebo in the treatment of warts (Ref. 1).

Based on the above, the agency is adding this formulation to the final monograph by revising proposed § 358.110 to add paragraph (c) for the active ingredient, "Salicylic acid 15 percent in a karaya gum, glycol plaster vehicle." The agency is also revising proposed § 358.110 to add a new paragraph (d)(3) as folllows: *"For products containing salicylic acid identified in § 358.110(c).* 'Wash affected area.' (Optional: 'May soak wart in warm water for 5 minutes.') 'Dry area thoroughly.' (If appropriate: 'Cut plaster to fit wart.') "Apply medicated plaster at bedtime, leave in place for at least 8 hours; in the morning, remove plaster and discard. Repeat procedure every 24

hours as needed (until wart is removed) for up to 12 weeks.' "

Reference

(1) Comment No. RPT 2, Docket No. 80N-0236, Dockets Management Branch.

14. One comment noted its continuing position that FDA cannot legally and should not, as a matter of policy, prescribe exclusive lists of terms from which indications for use for OTC drug products must be drawn and prohibit alternative OTC drug labeling terminology to describe such indications which is truthful, not misleading, and intelligible to the consumer. The comment referred to its oral and written testimony submitted to FDA in connection with the September 29, 1982 hearing on the exclusivity policy.

In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES," plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (e.g., statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, *e.g.*, 21 CFR 201.63 or 330.1(g). The final rule in this document is subject to the labeling provisions in § 330.1(c)(2).

15. One comment requested the deletion of a portion of the directions proposed in § 358.150(d). The comment contended that directing patients to "Gently remove softened areas of the wart by rubbing with a wash cloth or emery board," and "Do not rub hard enough to cause bleeding," was not necessary and may not be in the best interest of the consumer. The comment explained that the consumer did not need to remove softened areas of the wart by rubbing and that the product would be effective without rubbing the wart as proposed in § 358.150(d). The comment contended that improper use of an emery board or washcloth could easily cause bleeding and subsequent infection.

This comment addressed directions proposed in the tentative final monograph published on September 3, 1982, and was received prior to publication of the reproposed tentative final monograph on March 27, 1987 (52 FR 9992). In that reproposal, the agency revised the directions proposed in § 358.150(d) and no longer included any directions about removing softened areas of the wart by rubbing. Thus, the comment's request was taken care of by the reproposed tentative final monograph.

16. One comment requested the deletion of the phrase in proposed § 358.150(d) that reads "preferably by encircling the wart with a ring of petrolatum." The comment contended that including only "petrolatum" in the warning may create the mistaken belief that petrolatum is the only acceptable protection. The comment added that such was not the Panel's finding, and many other types of protection could be used. Further, the comment argued that the word petrolatum may not be understood by consumers and, hence, may cause confusion. The comment concluded that the first part of the proposed directions statement, i.e., "Keep product away from surrounding skin" is sufficient to provide the consumer with directions to ensure correct usage of the product.

This comment addressed directions proposed in the tentative final monograph published on September 3, 1982, and was received prior to publication of the proposed tentative final monograph on March 27, 1987 (52 FR 9992). In that reproposal, the agency no longer included any directions about encircling the wart with a ring of petrolatum. In addition, the agency also did not include a direction to "keep the product away from surrounding skin." This decision was based on a discussion that appeared in the tentative final monograph for OTC corn and callus remover drug products, where the agency stated that recent studies on the effect of salicylic acid on normal skin have demonstrated that salicylic acid primarily reduces the intercellular cohesiveness of the horny cells and has no effect on the mitotic activity of the normal epidermis. (See 52 FR 5412 at 5416.) Thus, the agency determined that the warning regarding avoiding contact with the surrounding skin is not necessary. Accordingly, the comment's request was taken care of by the reproposed tentative final monograph.

II. Summary of Significant Changes From the Proposed Rule

1. The agency has determined that a hydroscopic karaya gum pad with polypropylene backing meets the definition of a "plaster vehicle" in this final monograph. (See comment 5 above.) The agency is adding "salicylic acid 15 percent in a karaya gum, glycol plaster vehicle" to the list of active ingredients in § 358.110 and directions for this ingredient in § 358.150(d). (See comment 13 above.)

2. The agency has determined that a vehicle containing pyroxylin, volatile solvents, and a plasticizer meets the definition of a "collodion-like" vehicle in this final monograph. (See comment 7 above.)

3. The warnings proposed in § 358.150(c)(1) (ii) and (iii) are being combined, revised, and redesignated as § 358.150(c)(1)(ii). The warnings proposed in § 358.150(c)(1) (iv) and (v) are now redesignated as paragraphs (iii) and (iv). (See comment 11 above.)

4. The agency is revising the directions proposed in § 358.150(d) (1) and (2) to give manufacturers the option of including information about soaking the wart for 5 minutes in warm water prior to application of the wart remover drug product. (See comment 12 above.)

III. The Agency's Final Conclusions on OTC Wart Remover Drug Products

Based on the available evidence, the agency is issuing a final monograph establishing conditions under which OTC wart remover drug products are generally recognized as safe and effective and not misbranded. Specifically, the agency has determined that the only ingredients that meet monograph conditions are salicylic acid 12 to 40 percent in a plaster vehicle, salicylic acid 5 to 17 percent in a collodion-like vehicle, and salicylic acid 15 percent in a karaya gum, glycol plaster vehicle. All other ingredients for wart removal that were considered in this rulemaking are considered nonmonograph ingredients, i.e., acetic acid, glacial acetic acid, ascorbic acid, benzocaine, calcium pantothenate, camphor, castor oil, iodine, lactic acid, and menthol. Any drug product marketed for use as an OTC wart remover that is not in conformance with the monograph (21 CFR part 358, subpart B) is considered a new drug within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(p)) and misbranded under

section 502 of the act (21 U.S.C. 352) and can not be marketed for this use unless it is the subject of an approved application. An appropriate citizen petition to amend the monograph may also be submitted under 21 CFR 10.30.

No comments were received in response to the agency's request for specific comment on the economic impact of this rulemaking (52 FR 9993). The agency has examined the economic consequences of this final rule in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this final rule for OTC wart remover drug products, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96-354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC wart remover drug products is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

The agency has determined under 21 CFR 25.24(c)(6) 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.

List of Subjects in 21 CFR Part 358

Labeling, Over-the-counter drugs, Wart remover drug products.

Therefore, under the Federal Food, Drug, and Cosmetic Act, subchapter D of chapter I of title 21 of the Code of Federal Regulations is amended by adding new part 358 as follows:

PART 358—MISCELLANEOUS EXTERNAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—[Reserved]

Subpart B—Wart Remover Drug Products

Sec.

Authority: Sections 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

Subpart A—[Reserved]

Subpart B—Wart Remover Drug Products

§ 358.101 Scope.

(a) An over-the-counter wart remover drug product in a form suitable for topical application is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each of the general conditions established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 358.103 Definitions.

As used in this subpart:

(a) *Wart remover drug product.* A topical agent used for the removal of common or plantar warts.

(b) *Collodion-like vehicle.* A solution containing pyroxylin (nitrocellulose) in an appropriate nonaqueous solvent that leaves a transparent cohesive film when applied to the skin in a thin layer.

(c) *Plaster vehicle.* A fabric, plastic, or other suitable backing material in which medication is usually incorporated for topical application to the skin.

§ 358.110 Wart remover active ingredients.

The product consists of any of the following active ingredients within the specified concentration and in the dosage form established for each ingredient.

(a) Salicylic acid 12 to 40 percent in a plaster vehicle.

(b) Salicylic acid 5 to 17 percent in a collodion-like vehicle.

(c) Salicylic acid 15 percent in a karaya gum, glycol plaster vehicle.

§ 358.150 Labeling of wart remover drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as a "wart remover."

(b) *Indications.* The labeling of the product states, under the heading "Indications," any of the phrases listed in paragraph (b) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) "For the removal of common warts. The common wart is easily recognized by the rough 'cauliflower-like' appearance of the surface."

(2) "For the removal of plantar warts on the bottom of the foot. The plantar wart is recognized by its location only on the bottom of the foot, its tenderness, and the interruption of the footprint pattern."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing any ingredient identified in § 358.110.* (i) "For external use only."

(ii) "Do not use this product on irritated skin, on any area that is infected or reddened, if your are a diabetic, or if you have poor blood circulation."

(iii) "If discomfort persists, see your doctor."

(iv) "Do not use on moles, birthmarks, warts with hair growing from them, genital warts, or warts on the face or mucous membranes."

(2) *For any product formulated in a flammable vehicle.* (i) The labeling should contain an appropriate flammability signal word, e.g. "extremely flammable," "flammable," "combustible," consistent with 16 CFR 1500.3(b)(10).

(ii) "Keep away from fire or flame."

(3) *For any product formulated in a volatile vehicle.* "Cap bottle tightly and store at room temperature away from heat."

(4) *For any product formulated in a collodion-like vehicle.* (i) "If product gets into the eye, flush with water for 15 minutes."

(ii) "Avoid inhaling vapors."

(d) *Directions.* The labeling of the product contains the following information under the heading "Directions":

(1) *For products containing salicylic acid identified in § 358.110(a).* "Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly." (If appropriate: "Cut plaster to fit wart.") "Apply medicated plaster. Repeat procedure every 48 hours as needed (until wart is removed) for up to 12 weeks."

(2) *For products containing salicylic acid identified in § 358.110(b).* "Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly." Apply one drop at a time to sufficiently cover each wart. Let dry. Repeat this procedure once or twice daily as needed (until wart is removed) for up to 12 weeks."

(3) *For products containing salicyclic acid identified in § 358.110(c).* "Wash affected area." (Optional: "May soak wart in warm water for 5 minutes.") "Dry area thoroughly." (If appropriate: "Cut plaster to fit wart.") "Apply medicated plaster at bedtime, leave in place for at least 8 hours; in the morning, remove plaster and discard. Repeat procedure every 24 hours as needed (until wart is removed) for up to 12 weeks."

(e) The word "physician" may be substituted for the word "doctor" in any of the labeling statements in this section.

(f) The phrase "or podiatrist" may be used in addition to the word "doctor" in any of the labeling statements in this section when a product is labeled with the indication identified in § 358.150(b)(2).

Dated: June 27, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

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