

Presidential Documents

Title 3—THE PRESIDENT

Proclamation 3655

ARMED FORCES DAY

By the President of the United States of America

A Proclamation

WHEREAS the safety of our cherished freedom rests in large measure upon the capabilities of our Armed Forces to forestall totalitarian aggression; and

WHEREAS the Armed Forces of the United States serve as a unified team, at home and at outposts throughout the world, insuring our own security and the security of our friends abroad, and fostering the settlement of international differences by peaceful processes; and

WHEREAS enlightened understanding and unstinting support of our Armed Forces by an informed American people are vital to the strength and vigor of our Armed Forces; and

WHEREAS our soldiers, sailors, airmen, marines, and coastguardsmen, from whom we ask so much, are the cornerstone of our military might and richly deserve to have a special day set aside in their honor:

NOW, THEREFORE, I, LYNDON B. JOHNSON, President of the United States of America and Commander in Chief of the Armed Forces of the United States, do hereby proclaim the third Saturday of May in 1965 and the third Saturday of May in each succeeding year as Armed Forces Day.

I direct the Secretary of Defense on behalf of the Army, the Navy, the Air Force, and the Marine Corps, and the Secretary of the Treasury on behalf of the Coast Guard, to designate that day each year for appropriate observances. The Secretary of Defense, as my personal representative, shall be responsible for the program contemplated by this proclamation and for soliciting the participation and cooperation in its execution by civil authorities and distinguished private citizens.

I invite the Governors of the States, the Commonwealth of Puerto Rico, and other areas subject to the jurisdiction of the United States, and the Commissioners of the District of Columbia, to provide for the observance of Armed Forces Day within their jurisdictions each year in an appropriate manner designed to enhance public understanding and appreciation of the Armed Forces of the United States as defenders of freedom at home and abroad.

I call upon my fellow Americans to display the flag of the United States at their homes on Armed Forces Day. I invite them to take part in observances planned by personnel of the Armed Forces as a report to the Nation which they are sworn to protect.

Proclamation No. 3172 of March 5, 1957, and Proclamation No. 3399 of March 18, 1961, are hereby superseded.

IN WITNESS WHEREOF, I have hereunto set my hand and caused the Seal of the United States of America to be affixed.

DONE at the City of Washington this seventh day of May in the year of our Lord nineteen hundred and sixty-five, and of the Independence of the United States of America the one hundred and eighty-ninth.

LYNDON B. JOHNSON

By the President:

DEAN RUSK,
Secretary of State.

[F.R. Doc. 65-5014; Filed, May 10, 1965; 10:28 a.m.]

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Executive Order 11222

PRESCRIBING STANDARDS OF ETHICAL CONDUCT FOR GOVERNMENT OFFICERS AND EMPLOYEES

By virtue of the authority vested in me by Section 301 of Title 3 of the United States Code, and as President of the United States, it is hereby ordered as follows:

PART I—POLICY

SECTION 101. Where government is based on the consent of the governed, every citizen is entitled to have complete confidence in the integrity of his government. Each individual officer, employee, or adviser of government must help to earn and must honor that trust by his own integrity and conduct in all official actions.

PART II—STANDARDS OF CONDUCT

SECTION 201. (a) Except in accordance with regulations issued pursuant to subsection (b) of this section, no employee shall solicit or accept, directly or indirectly, any gift, gratuity, favor, entertainment, loan, or any other thing of monetary value, from any person, corporation, or group which—

(1) has, or is seeking to obtain, contractual or other business or financial relationships with his agency;

(2) conducts operations or activities which are regulated by his agency; or

(3) has interests which may be substantially affected by the performance or nonperformance of his official duty.

(b) Agency heads are authorized to issue regulations, coordinated and approved by the Civil Service Commission, implementing the provisions of subsection (a) of this section and to provide for such exceptions therein as may be necessary and appropriate in view of the nature of their agency's work and the duties and responsibilities of their employees. For example, it may be appropriate to provide exceptions (1) governing obvious family or personal relationships where the circumstances make it clear that it is those relationships rather than the business of the persons concerned which are the motivating factors—the clearest illustration being the parents, children or spouses of federal employees; (2) permitting acceptance of food and refreshments available in the ordinary course of a luncheon or dinner or other meeting or on inspection tours where an employee may properly be in attendance; or (3) permitting acceptance of loans from banks or other financial institutions on customary terms to finance proper and usual activities of employees, such as home mortgage loans. This section shall be effective upon issuance of such regulations.

(c) It is the intent of this section that employees avoid any action, whether or not specifically prohibited by subsection (a), which might result in, or create the appearance of—

(1) using public office for private gain;

(2) giving preferential treatment to any organization or person;

(3) impeding government efficiency or economy;

(4) losing complete independence or impartiality of action;

(5) making a government decision outside official channels; or

(6) affecting adversely the confidence of the public in the integrity of the Government.

SEC. 202. An employee shall not engage in any outside employment, including teaching, lecturing, or writing, which might result in a conflict, or an apparent conflict, between the private interests of the

employee and his official government duties and responsibilities, although such teaching, lecturing, and writing by employees are generally to be encouraged so long as the laws, the provisions of this order, and Civil Service Commission and agency regulations covering conflict of interest and outside employment are observed.

SEC. 203. Employees may not (a) have direct or indirect financial interests that conflict substantially, or appear to conflict substantially, with their responsibilities and duties as Federal employees, or (b) engage in, directly or indirectly, financial transactions as a result of, or primarily relying upon, information obtained through their employment. Aside from these restrictions, employees are free to engage in lawful financial transactions to the same extent as private citizens. Agencies may, however, further restrict such transactions in the light of the special circumstances of their individual missions.

SEC. 204. An employee shall not use Federal property of any kind for other than officially approved activities. He must protect and conserve all Federal property, including equipment and supplies, entrusted or issued to him.

SEC. 205. An employee shall not directly or indirectly make use of, or permit others to make use of, for the purpose of furthering a private interest, official information not made available to the general public.

SEC. 206. An employee is expected to meet all just financial obligations, especially those—such as Federal, State, or local taxes—which are imposed by law.

PART III—STANDARDS OF ETHICAL CONDUCT FOR SPECIAL GOVERNMENT EMPLOYEES

SECTION 301. This part applies to all "special Government employees" as defined in Section 202 of Title 18 of the United States Code, who are employed in the Executive Branch.

SEC. 302. A consultant, adviser or other special Government employee must refrain from any use of his public office which is motivated by, or gives the appearance of being motivated by, the desire for private gain for himself or other persons, including particularly those with whom he has family, business, or financial ties.

SEC. 303. A consultant, adviser, or other special Government employee shall not use any inside information obtained as a result of his government service for private personal gain, either by direct action on his part or by counsel, recommendations or suggestions to others, including particularly those with whom he has family, business, or financial ties.

SEC. 304. An adviser, consultant, or other special Government employee shall not use his position in any way to coerce, or give the appearance of coercing, another person to provide any financial benefit to him or persons with whom he has family, business, or financial ties.

SEC. 305. An adviser, consultant, or other special Government employee shall not receive or solicit from persons having business with his agency anything of value as a gift, gratuity, loan or favor for himself or persons with whom he has family, business, or financial ties while employed by the government or in connection with his work with the government.

SEC. 306. Each agency shall, at the time of employment of a consultant, adviser, or other special Government employee require him to supply it with a statement of all other employment. The statement shall list the names of all the corporations, companies, firms, State or local governmental organizations, research organizations and educational or other institutions in which he is serving as employee, officer, member, owner, director, trustee, adviser, or consultant. In addition, it shall list such other financial information as the appointing department or agency shall decide is relevant in the light of the duties the appointee is to perform. The appointee may, but need not, be required to reveal precise amounts of investments. The statement shall be kept current throughout the period during which the employee is on the Government rolls.

PART IV—REPORTING OF FINANCIAL INTERESTS

SECTION 401. (a) Not later than ninety days after the date of this order, the head of each agency, each Presidential appointee in the Executive Office of the President who is not subordinate to the head of an agency in that Office, and each full-time member of a committee, board, or commission appointed by the President, shall submit to the Chairman of the Civil Service Commission a statement containing the following:

(1) A list of the names of all corporations, companies, firms, or other business enterprises, partnerships, nonprofit organizations, and educational or other institutions—

(A) with which he is connected as an employee, officer, owner, director, trustee, partner, adviser, or consultant; or

(B) in which he has any continuing financial interests, through a pension or retirement plan, shared income, or otherwise, as a result of any current or prior employment or business or professional association; or

(C) in which he has any financial interest through the ownership of stocks, bonds, or other securities.

(2) A list of the names of his creditors, other than those to whom he may be indebted by reason of a mortgage on property which he occupies as a personal residence or to whom he may be indebted for current and ordinary household and living expenses.

(3) A list of his interests in real property or rights in lands, other than property which he occupies as a personal residence.

(b) Each person who enters upon duty after the date of this order in an office or position as to which a statement is required by this section shall submit such statement not later than thirty days after the date of his entrance on duty.

(c) Each statement required by this section shall be kept up to date by submission of amended statements of any changes in, or additions to, the information required to be included in the original statement, on a quarterly basis.

SEC. 402. The Civil Service Commission shall prescribe regulations, not inconsistent with this part, to require the submission of statements of financial interests by such employees, subordinate to the heads of agencies, as the Commission may designate. The Commission shall prescribe the form and content of such statements and the time or times and places for such submission.

SEC. 403. (a) The interest of a spouse, minor child, or other member of his immediate household shall be considered to be an interest of a person required to submit a statement by or pursuant to this part.

(b) In the event any information required to be included in a statement required by or pursuant to this part is not known to the person required to submit such statement but is known to other persons, the person concerned shall request such other persons to submit the required information on his behalf.

(c) This part shall not be construed to require the submission of any information relating to any person's connection with, or interest in, any professional society or any charitable, religious, social, fraternal, educational, recreational, public service, civic, or political organization or any similar organization not conducted as a business enterprise and which is not engaged in the ownership or conduct of a business enterprise.

SEC. 404. The Chairman of the Civil Service Commission shall report to the President any information contained in statements required by Section 401 of this part which may indicate a conflict between the financial interests of the official concerned and the performance of his services for the Government. The Commission shall report, or by regulation require reporting, to the head of the agency concerned any information contained in statements submitted pursuant to regulations issued under Section 402 of this part which may indicate a conflict between the financial interests of the officer or employee concerned and the performance of his services for the Government.

SEC. 405. The statements and amended statements required by or pursuant to this part shall be held in confidence, and no information as to the contents thereof shall be disclosed except as the Chairman of the Civil Service Commission or the head of the agency concerned may determine for good cause shown.

SEC. 406. The statements and amended statements required by or pursuant to this part shall be in addition to, and not in substitution for, or in derogation of, any similar requirement imposed by law, regulation, or order. The submission of a statement or amended statements required by or pursuant to this part shall not be deemed to permit any person to participate in any matter in which his participation is prohibited by law, regulation, or order.

PART V—DELEGATING AUTHORITY OF THE PRESIDENT UNDER SECTIONS 205 AND 208 OF TITLE 18 OF THE UNITED STATES CODE RELATING TO CONFLICTS OF INTEREST

SECTION 501. As used in this part, "department" means an executive department, "agency" means an independent agency or establishment or a Government corporation, and "head of an agency" means, in the case of an agency headed by more than one person, the chairman or comparable member of such agency.

SEC. 502. There is delegated, in accordance with and to the extent prescribed in Sections 503 and 504 of this part, the authority of the President under Sections 205 and 208(b) of Title 18, United States Code, to permit certain actions by an officer or employee of the Government, including a special Government employee, for appointment to whose position the President is responsible.

SEC. 503. Insofar as the authority of the President referred to in Section 502 extends to any appointee of the President subordinate to or subject to the chairmanship of the head of a department or agency, it is delegated to such department or agency head.

SEC. 504. Insofar as the authority of the President referred to in Section 502 extends to an appointee of the President who is within or attached to a department or agency for purposes of administration, it is delegated to the head of such department or agency.

SEC. 505. Notwithstanding any provision of the preceding sections of this part to the contrary, this part does not include a delegation of the authority of the President referred to in Section 502 insofar as it extends to:

- (a) The head of any department or agency in the Executive Branch;
- (b) Presidential appointees in the Executive Office of the President who are not subordinate to the head of an agency in that Office; and
- (c) Presidential appointees to committees, boards, commissions, or similar groups established by the President.

PART VI—PROVIDING FOR THE PERFORMANCE BY THE CIVIL SERVICE COMMISSION OF CERTAIN AUTHORITY VESTED IN THE PRESIDENT BY SECTION 1753 OF THE REVISED STATUTES

SECTION 601. The Civil Service Commission is designated and empowered to perform, without the approval, ratification, or other action of the President, so much of the authority vested in the President by Section 1753 of the Revised Statutes of the United States (5 U.S.C. 631) as relates to establishing regulations for the conduct of persons in the civil service.

SEC. 602. Regulations issued under the authority of Section 601 shall be consistent with the standards of ethical conduct provided elsewhere in this order.

PART VII—GENERAL PROVISIONS

SECTION 701. The Civil Service Commission is authorized and directed, in addition to responsibilities assigned elsewhere in this order:

- (a) To issue appropriate regulations and instructions implementing Parts II, III, and IV of this order;
- (b) To review agency regulations from time to time for conformance with this order; and

(c) To recommend to the President from time to time such revisions in this order as may appear necessary to ensure the maintenance of high ethical standards within the Executive Branch.

SEC. 702. Each agency head is hereby directed to supplement the standards provided by law, by this order, and by regulations of the Civil Service Commission with regulations of special applicability to the particular functions and activities of his agency. Each agency head is also directed to assure (1) the widest possible distribution of regulations issued pursuant to this section, and (2) the availability of counseling for those employees who request advice or interpretation.

SEC. 703. The following are hereby revoked:

- (a) Executive Order No. 10939 of May 5, 1961.
- (b) Executive Order No. 11125 of October 29, 1963.
- (c) Section 2(a) of Executive Order No. 10530 of May 10, 1954.
- (d) White House memorandum of July 20, 1961, on "Standards of Conduct for Civilian Employees."
- (e) The President's Memorandum of May 2, 1963, "Preventing Conflicts of Interest on the Part of Special Government Employees." The effective date of this revocation shall be the date of issuance by the Civil Service Commission of regulations under Section 701(a) of this order.

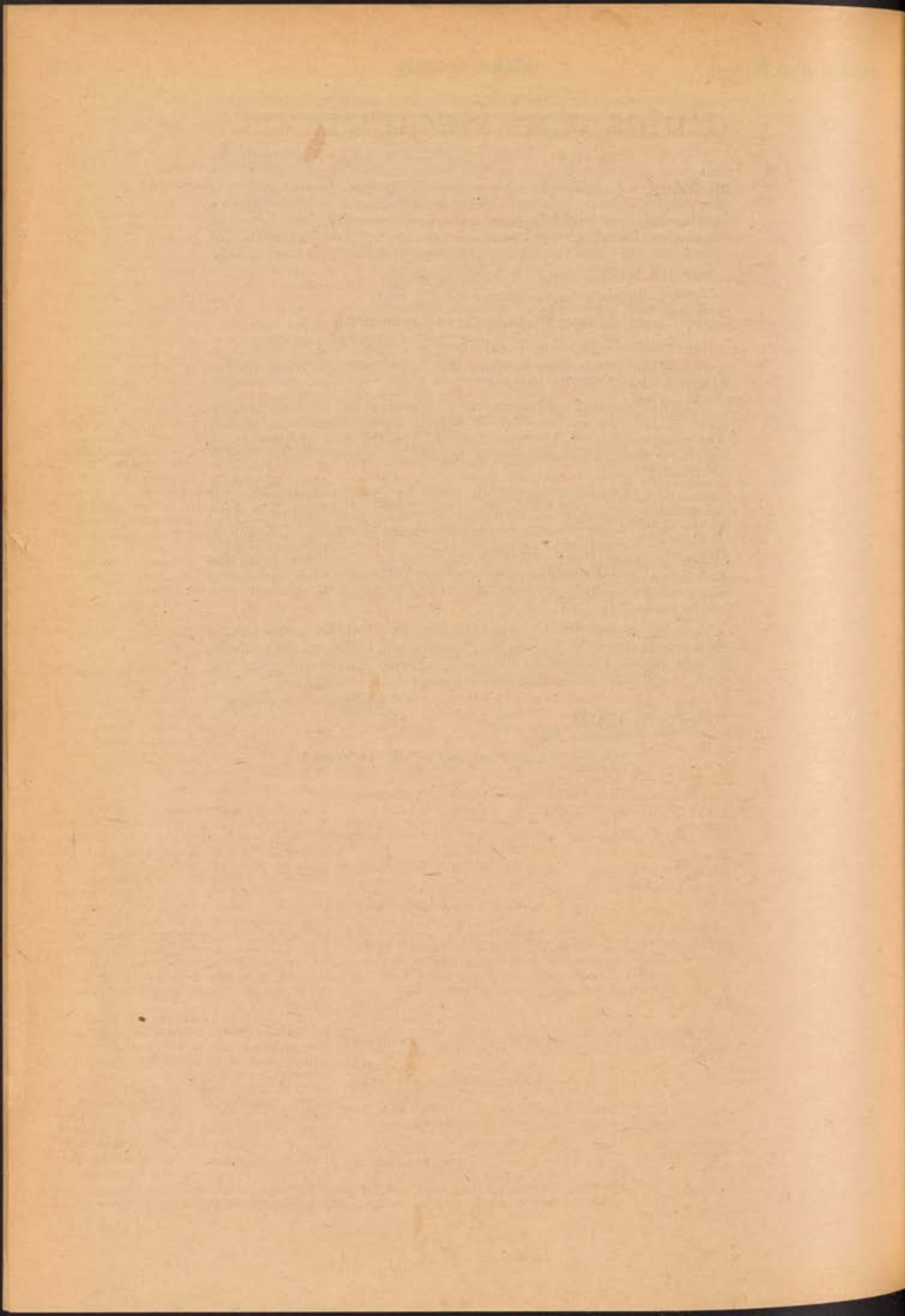
SEC. 704. All actions heretofore taken by the President or by his delegates in respect of the matters affected by this order and in force at the time of the issuance of this order, including any regulations prescribed or approved by the President or by his delegates in respect of such matters, shall, except as they may be inconsistent with the provisions of this order or terminate by operation of law, remain in effect until amended, modified, or revoked pursuant to the authority conferred by this order.

SEC. 705. As used in this order, and except as otherwise specifically provided herein, the term "agency" means any executive department, or any independent agency or any Government corporation; and the term "employee" means any officer or employee of an agency.

LYNDON B. JOHNSON

THE WHITE HOUSE,
May 8, 1965.

[F.R. Doc. 65-5018; Filed, May 10, 1965; 10:39 a.m.]



Rules and Regulations

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

PART 133—DRUGS; CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURE, PROCESSING, PACKING, OR HOLDING

Medicated Animal Feeds; Final Order

In the matter of the promulgation of regulations to establish criteria for current good manufacturing practice in the manufacture, processing, packing, or holding of medicated animal feed:

Having considered the comments, objections, and suggestions filed in response to the notice of proposed rule-making in the above-identified matter published in the FEDERAL REGISTER of August 13, 1964 (29 F.R. 11628), the Commissioner of Food and Drugs has concluded that the proposed regulations should be issued, incorporating some of the suggested changes in whole or in part, as shown by the order hereinafter set forth. Therefore, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 501(a)(2)(B), 701(a); 52 Stat. 1050 as amended 76 Stat. 780, 781; 1055; 21 U.S.C. 351(a)(2)(B), 371(a)), and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (21 CFR 2.90): It is ordered, That Part 133 be amended as follows:

1. Section 133.1 is amended by adding thereto a new paragraph (c) as follows:

§ 133.1 Definitions.

(c) As used in this Part 133, the term "medicated feed" means any "complete feed," "feed additive supplement," or "feed additive concentrate," as defined in § 121.200 of this chapter, which feed contains one or more drugs as defined in section 201(g) of the act. The term "medicated feed" does not include any undiluted drug of "premix," as defined in § 121.200 of this chapter, intended for manufacturing use in the production of a medicated feed, since these are subject to §§ 133.3-133.14, inclusive.

2. Part 133 is amended by adding thereto the following new sections under the center heading indicated:

MEDICATED FEEDS; MANUFACTURING PRACTICE

Sec.	
133.100	Current good manufacturing practice.
133.101	Buildings.
133.102	Equipment.
133.103	Personnel.
133.104	Components.
133.105	Formula and production records.
133.106	Production and control procedures.
133.107	Packaging and labeling.
133.108	Laboratory controls.
133.109	Distribution records.
133.110	Complaint files.

MEDICATED FEEDS; MANUFACTURING PRACTICE

§ 133.100 Current good manufacturing practice.

The criteria in §§ 133.101-133.110, inclusive, shall apply in determining whether the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or holding of a medicated feed conform to or are operated or administered in conformity with current good manufacturing practice to assure that a medicated feed meets the requirements of the act as to safety, and has the identity and strength, and meets the quality and purity characteristics which it purports or is represented to possess, as required by section 501(a)(2)(B) of the act. The regulations in this Part 133 permit the use of precision, automatic, mechanical, or electronic equipment in the production of a medicated feed when adequate inspection and checking procedures are used to assure proper performance.

§ 133.101 Buildings.

Buildings in which medicated feeds are manufactured, processed, packaged, labeled, or held shall be maintained in a reasonably clean and orderly manner and shall be of suitable size, construction, and location in relation to surroundings to facilitate maintenance and operation for their intended purpose. The buildings shall:

(a) Provide adequate space for the orderly placement of equipment and materials used in any of the following operations for which they are employed, to minimize any risk of mixups between different medicated feeds, their components, packaging, or labeling:

(1) The receipt, control, and storage of components.

(2) Any manufacturing and processing operations performed on the medicated feed.

(3) Any packaging and labeling operations.

(4) Storage of containers, packaging materials, labeling, and finishing products.

(b) Provide adequate lighting and other physical facilities necessary to prevent unsafe contamination of raw materials and finished products before, during, and after production.

(c) Provide for adequate washing, cleaning, toilet, and locker facilities.

Work areas and equipment used for the production of medicated feeds or for the storage of the components of medicated feeds shall not be used for the production, mixing, or storage of finished or unfinished insecticides, fungicides, or rodenticides or their components.

§ 133.102 Equipment.

Equipment used for the manufacture, processing, packaging, bulk shipment, labeling, holding, or control of medicated feeds or their components shall be main-

tained in a reasonably clean and orderly manner and shall be of suitable design, size, construction, and location in relation to surroundings to facilitate maintenance and operation for its intended purpose. The equipment shall:

(a) Be so constructed that any surfaces that come into contact with medicated feeds are suitable, in that they are not reactive, additive, or absorptive to an extent that significantly affects the identity, strength, quality, or purity of the medicated feed or its components.

(b) Be so constructed that any substance required for the operation of the equipment, such as lubricants, coolants, etc., may be employed without hazard of becoming an unsafe additive to the medicated feed.

(c) Be constructed to facilitate adjustment, cleaning, and maintenance, and to assure uniformity of production and reliability of control procedures and to assure the exclusion from medicated feeds of unsafe contamination, including cross-contamination from manufacturing operations.

(d) Be suitably grounded electrically to prevent lack of uniform mixing due to electrically charged particles.

(e) Be of suitable size and accuracy for use in any intended measuring, mixing, or weighing operations.

§ 133.103 Personnel.

The key employees and/or consultants responsible for the formulation, manufacture, and control of the medicated feed shall have a background of education or experience or a combination thereof that is adequate to assure proper composition and labeling of the medicated feeds.

§ 133.104 Components.

(a) Drug components, including undiluted drugs and any intermediate mixes containing drugs used in the manufacture and processing of medicated feeds, shall be received, stored, handled, and otherwise controlled in a manner to maintain the integrity and identification of such articles. Appropriate receipt and inventory records shall be maintained for 1 year and such records shall show the origin of any drug components, the batches in which they were used, and the results of any testing of them by or on behalf of the medicated-feed manufacturer.

(b) Nondrug components shall be stored and otherwise handled in a manner to avoid unsafe contamination, including cross-contamination from manufacturing operations.

(c) Statements relating to the identification and the quantitative composition appearing on the labels of undiluted drugs or other drug components received by the medicated-feed manufacturer from other suppliers may be relied upon by the medicated-feed manufacturer as acceptable evidence of the identity and composition of the drug or drug com-

ponents in lieu of actual testing of each such drug or drug component if such reliance is made in good faith.

§ 133.105 Formula and production records.

(a) For each medicated feed, a master formula record or card shall be prepared, checked, and maintained by a responsible key employee and retained for at least 1 year after production of the last batch. The formula record or card shall include at least the following:

(1) The name of the medicated feed, together with any other information necessary for the correct identification of the feed.

(2) The weight or measure of each ingredient, adequately identified, to be used in manufacturing a stated weight of the medicated feed.

(3) A copy, description, or notation adequately identifying the label, labeling, or placard necessary to be used on or with the complete medicated feed.

(4) Manufacturing instructions for each medicated feed produced on a batch or continuous operation basis, including mixing steps, mixing times, and batch formulas that have been determined to yield an adequately mixed medicated feed; and in the case of medicated feeds produced by continuous production run, any additional manufacturing directions including, when indicated, the settings of equipment that have been determined to yield an adequately mixed medicated feed of the specified formula.

(5) Appropriate control directions, including the manner and frequency with which any necessary samples of the medicated feed are to be taken for specified laboratory tests, the criteria for using laboratory test results to change formulations or manufacturing procedures, and the procedures to be observed to avoid unsafe contamination of the medicated feed with other medicated feeds or drug components.

(b) A production record shall be prepared for each batch or run of medicated feed produced, and shall be retained for at least 1 year. The production record shall include:

(1) Product identification, date of production, and endorsement by a responsible individual.

(2) A record of the quantity of drug components used.

(3) A record of the quantity of medicated feed produced.

(c) In the case of a customer-formula feed made to the specifications of a customer, the formula and production records required by this section may consist of copies of customers' purchase orders and sellers' invoices bearing the information required by this section.

§ 133.106 Production and control procedures.

Production and control procedures shall include all reasonable precautions, including the following, to assure that the medicated feeds produced are of proper composition and labeling:

(a) Each critical step in the process, such as the selection, weighing, and measuring of components; the addition of drugs or components during the process; the control of mixing times; the ad-

justment of the equipment involved in continuous production processes; and the determination of the finished yield, shall be performed in a manner that has been determined by appropriate methods, including laboratory testing of the medicated feed, to be adequate to assure the integrity of the final product. If such steps in the processing are controlled by precision, automatic, mechanical, or electronic equipment, provision shall be made to adequately check its performance.

(b) All containers to be used for undiluted drugs, drug components, intermediate mixtures, and finished feeds shall be received, adequately identified, and properly stored and handled in a manner adequate to prevent mixups or contamination.

(c) Equipment, including dust-control and other equipment, such as that used for holding and returning recovered or flush-out materials back into production, shall be maintained and operated in such a manner as to prevent unsafe contamination of the medicated feed.

(d) The steps used to prevent unsafe contamination of medicated feed include one or more of the following, or other equally effective procedures:

(1) Cleaning of those parts of storage, mixing, conveying, and any other equipment coming in contact with the drug component of the medicated feed for the purpose of cleaning out of the equipment any drug, drug component, or medicated feed prior to the use of the same equipment for the production of a different medicated feed.

(2) The cleaning of the equipment as required in subparagraph (1) of this paragraph, may be achieved by flushing all feed-contacting surfaces of such equipment used in the production of a medicated feed with a quantity of an appropriate drug-free feedstuff that has been found sufficient to remove any significant quantity of a drug component or an intermediate mix or complete medicated feed prior to the production of a different medicated feed. The yield from any such flushing operation may be incorporated in appropriate amounts in the subsequent production of a medicated feed intended to contain the same drug component (or components) to produce a complete medicated feed conforming to its composition and labeling specifications.

(e) If there is sequential production of batches of a medicated feed containing the same drug component (or components) at the same or lower levels, there shall be sufficient safeguards to avoid any buildup above the specified levels of the drug components in any of the batches of the complete feed.

(f) A sampling and assay schedule on the finished medicated feed, or a schedule at least as reliable, for checking on the composition of the finished article shall be applied as follows:

(1) In the case of a medicated feed that requires an approved new-drug application or antibiotic form 10 for its manufacture and marketing, the schedule of assays established in such application shall be used.

(2) In the case of a medicated feed that does not require an approved new-

drug application or antibiotic form 10 for its marketing, three appropriately drawn samples from each 400 tons of such medicated feeds produced shall be taken at appropriately spaced intervals over the production period, and, in any event, not less than three such samples of each particular medicated feed during any 1 year shall be collected and analyzed. For the purposes of this subparagraph, the term "each particular medicated feed" shall be construed to include all feeds containing the same drug component (or the same mixture of components) at different levels. The collection and analysis of samples shall be from the medicated feed containing the highest level of the drug component (or mixture of components).

(3) A medicated feed covered by subparagraph (2) of this paragraph shall be exempt from the prescribed sampling and analytical schedule under the following conditions:

(i) The manufacturing practices used in the production of the medicated feed were consistent with the regulations of this part; and

(ii) The manufacturer of the medicated feed has produced at least 3 batches of such feed conforming to composition and labeling specifications during the 1-year period immediately preceding the date of manufacture of the feed and during that period has not been notified by the Food and Drug Administration or any State regulatory official that his manufacturing practices were in conflict with section 501(a)(2)(B) of the act or the regulations of this part and has not distributed a medicated feed during that period which has been proceeded against under the act because of failure of such feed to comply with its composition or labeling requirements or which has been analyzed by any State official and found to be deficient; and

(iii) The medicated feed contains only, as the drug component (or components), a low-level growth-promotion antibiotic (or antibiotics) as provided by and in accordance with the regulations in Part 121 of this chapter; it was manufactured from a feed additive premix, feed additive concentrate, or feed additive supplement that, at the time of receipt by the medicated-feed manufacturer, bore a label, or was accompanied by labeling, containing a quantitative composition statement of its antibiotic content together with directions for its use in the manufacturing of a legal medicated feed; and the medicated-feed manufacturer, in good faith, relied upon and followed the feed additive premix, concentrate, or supplement label or labeling information and directions for use in the manufacturing of the medicated feed; or

(iv) The medicated feed contains only, as the drug component (or components), a drug (or drugs) as provided by and in accordance with the regulations in Part 121 of this chapter; it was manufactured from a feed additive concentrate or feed additive supplement that, at the time of receipt by the medicated-feed manufacturer, bore a label, or was accompanied by labeling, containing the quantitative composition of

its drug content together with directions for its use in the manufacturing of a legal medicated feed; and the medicated-feed manufacturer, in good faith, relied upon and followed the feed additive concentrate or supplement label or labeling information and directions for use in the manufacturing of the medicated feed; or

(v) The medicated feed contains only drug components as provided by and in accordance with the regulations in Part 121 of this chapter and was manufactured from a feed additive supplement, a low level growth-promotion antibiotic premix, a low level growth-promotion antibiotic concentrate, a feed additive concentrate, or a combination of any two of these used in accordance with the conditions set forth in subdivisions (ii), (iii), and (iv) of this subparagraph.

(g) Production and control procedures shall include provision for discontinuing distribution of any medicated feed found by the assay procedures, or any other controls performed, to fail to conform to appropriate specifications. Distribution of subsequent production shall not begin until it has been determined that proper control procedures have been established.

§ 133.107 Packaging and labeling.

Packaging and labeling operations shall be adequately performed and controlled to assure that only those medicated feeds made in compliance with established formula records and manufacturing and control directions shall be distributed; to prevent mixups between the medicated feeds during the packaging and labeling operations; and to assure that correct labeling is employed for the medicated feed. In the case of medicated feeds distributed in bulk, complete labeling shall accompany the shipment and be supplied to the consignee at the time of delivery. Such labeling may consist of an invoice or placard identifying the medicated feed and bearing adequate information for the safe and effective use of the medicated feed. Labels and labeling shall be received, handled, and stored in a manner that avoids labeling mixups. Previously used containers shall be adequately cleaned and labeled before reuse to avoid adulteration or misbranding.

§ 133.108 Laboratory controls.

Laboratory controls shall include the establishment of adequate specifications and test procedures to assure that the drug components and the finished medicated feeds conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(a) The establishment of master records containing appropriate specifications and a description of the test procedures used to check them for each kind of drug used in the manufacture of medicated feeds; this may consist of the manufacturer's or supplier's statement of specifications.

(b) The establishment of finished-product specifications for medicated feeds and a description of any necessary laboratory test procedures to check them, including methods of assay for the active drug ingredient.

(c) A determination that the drug components remain uniformly dispersed and stable in the medicated feed under ordinary conditions of shipment, storage, and use; this may consist of a supplier's or consultant's determination made on a feed of substantially the same formula.

(d) Adequate provision to check the reliability, accuracy, and precision of any laboratory test procedure used; the official Methods of Analysis of the Association of Official Agricultural Chemists, methods described in an official compendium, and any method, submitted as a part of a food additive petition or new-drug application, which has been accepted by the Food and Drug Administration shall be regarded as meeting this provision.

(e) Provision for the maintenance of the results of any assays, including dates and endorsement of analysts. Such records, together with records of analyses reported by any State feed control official shall be retained in the possession of the manufacturer or in the possession of a consulting laboratory operating in his behalf. Such records shall be maintained for a period of at least 1 year after distribution of the medicated feed has been completed.

§ 133.109 Distribution records.

Complete records shall be maintained for each shipment of medicated feeds in a manner that will facilitate the recall, diversion, or destruction of the medicated feed, if necessary. Such records shall be retained for at least 6 months after the date of the shipment, and shall include the name and address of the consignee, the date and quantity shipped, and the manufacturing dates, control numbers, or marks identifying the medicated feed shipped. If the medicated feed is held under control of the manufacturer for further shipment at establishments other than where produced, records as outlined in this section shall be maintained at these establishments.

§ 133.110 Complaint files.

The medicated-feed manufacturer shall evaluate by responsible key personnel each complaint received by him on a feed that is manufactured or distributed by him and, where indicated, make such further investigations or take such appropriate action as appears to be warranted in the circumstances. A record of complaints and the action taken by the feed manufacturer shall be maintained for a period of 2 years. If the medicated feed is the subject of an approved new-drug application held by the feed manufacturer, he shall make such reports as are required by § 130.13 of this chapter.

Effective date. This order shall be effective on the date of its publication in the FEDERAL REGISTER.

(Secs. 501(a)(2)(B), 701(a); 52 Stat. 1050 as amended 76 Stat. 780, 781; 1055; 21 U.S.C. 351(a)(2)(B), 371(a))

Dated: May 6, 1965.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 65-4979; Filed, May 10, 1965; 8:48 a.m.]

PART 121—FOOD ADDITIVES

Subpart C—Food Additives Permitted in Feed and Drinking Water of Animals or for the Treatment of Food-Producing Animals

TECHNICAL WHITE MINERAL OIL; UNIFORMITY OF NOMENCLATURE

In the matter of amending § 121.246, one comment was received with reference to the notice of proposed rulemaking published in the FEDERAL REGISTER of February 27, 1965 (30 F.R. 2605). This comment was directed to the specifications of technical white mineral oil as defined in § 121.2589. The objection contained in this comment has been resolved by an amendment to § 121.2589 which was promulgated by publication in the FEDERAL REGISTER of April 16, 1965 (30 F.R. 5475).

Accordingly, pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 409(d), 72 Stat. 1787; 21 U.S.C. 348(d)) and under the authority delegated to the Commissioner by the Secretary of Health, Education, and Welfare (21 CFR 2.90), the proposed amendment to § 121.246 is made effective without change. The introduction and paragraphs (a) and (c) of § 121.246 are revised to read as follows:

§ 121.246 Mineral oil.

Mineral oil may be safely used in animal feed, subject to the provisions of this section.

(a) Mineral oil, for the purpose of this section, is that complying with the definition and specifications contained in § 121.1146 (a) and (b) or in § 121.2589 (b) (1) (i) and (ii).

(c) The quantity of mineral oil used in animal feed shall not exceed 3.0 percent in mineral supplements, nor shall it exceed 0.06 percent of the total ration when present in feed or feed concentrates.

Any person who will be adversely affected by the foregoing order may at any time within 30 days from the date of its publication in the FEDERAL REGISTER file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 5440, 330 Independence Avenue SW., Washington, D.C., 20201, written objections thereto, preferably in quintuplicate. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought. Objections may be accompanied by a memorandum or brief in support thereof.

Effective date. This order shall be effective on the date of its publication in the FEDERAL REGISTER.

(Sec. 409(d), 72 Stat. 1787; 21 U.S.C. 348(d))

Dated: May 5, 1965.

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 65-4930; Filed, May 10, 1965; 8:47 a.m.]