as provided for in Rule XXII, nor any other action taken as thereby provided to prevent said initial decision becoming the decision of the Commission thirty days from service thereof upon the parties, said initial decision, including said order to cease and desist, accordingly, under the provisions of said Rule XXII became the decision of the Commission on April 21, 1952.

The said order to cease and desist is as follows:

It is ordered, That the respondents, National Coaching Service Institute, Inc., a corporation, and its officers, and Archie K. Babson, individually and as an officer of said corporation and also doing business under the names National Service Institute and Career Institute, and respondents' agents, representatives and employees, directly or through any corporate or other device, in connection with the offering for sale, sale and distribution in commerce, as "commerce" is defined in the Federal Trade Commission Act, of respondents' courses of study and instruction, do forthwith cease and desist from:

1. Using the word "Institute" or any simulation thereof as a part of respondents' corporate or trade names; or otherwise representing, directly or by implication, that respondents' school is a resident institution of higher learning.

2. Representing, directly or by implication:

(a) That respondents' school has any connection with the United States Civil Service or any other agency of the United States Government.

(b) That respondents' sales agents are representatives or employees of the United States Civil Service or have any connection therewith.

(c) That the completion of respondents' courses of study assures students of positions in the United States Civil Service or makes them eligible for appointment to such positions.

(d) That respondents have any power or authority to hold open for any person any position in the United States Civil Service.

(e) That it is necessary that persons seeking Civil Service positions take respondents' courses of study in order to qualify for or obtain such positions.

(f) That the examinations given by respondents are examinations for specific positions in the Civil Service.

(g) That all persons completing respondents' courses and passing Civil Service examinations will obtain positions immediately or within a short time.

(h) That positions obtained in the United States Civil Service will be at or near the place of residence of the employee.

(i) That Civil Service positions requiring certain physical, mental or educational qualifications or veterans' status may be obtained by persons not meeting such requirements.

(j) That the United States Civil Service Commission is looking to or relying upon respondents to locate persons to fill positions in the Civil Service.

By "Decision of the Commission and order to file report of compliance", Docket 5876, April 21, 1952, which announced and decreed fruition of said initial decision, report of compliance with the said order was required as follows:

It is ordered, That the respondents herein shall, within sixty (60) days after service upon them of this order, file with the Commission a report in writing setting forth in detail the manner and form in which they have complied with the order to cease and desist.

Issued: April 21, 1952.

By the Commission.

[SEAL] D. C. DANIEL, *Secretary.*

[F. R. Doc. 52-8170; Filed, July 24, 1952; 8:57 a. m.]

TITLE 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Federal Security Agency

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

DRUGS AND DEVICES; DIRECTIONS FOR USE; EXEMPTION FROM PRESCRIPTION REQUIREMENTS; FINAL ORDER

By virtue of the authority vested in the Federal Security Administrator by the provisions of sections 502 (f), 503 (b), and 701 (a) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1051, 1055; 65 Stat. 648; 21 U. S. C. 352 (f), 353 (b), 371 (a)), and after having considered all written comments filed with respect to the notice of proposed rule making published in the FEDERAL REGISTER on February 5, 1952 (17 F. R. 1130), the following regulations are promulgated.

1. Section 1.106 is revoked and a new § 1.106 is added to read as follows:

§ 1.106 *Drugs and devices; directions for use*—(a) *Adequate directions for use.* "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(2) Quantity of dose (including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions).

(3) Frequency of administration or application.

(4) Duration of administration or application.

(5) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).

(6) Route or method of administration or application.

(7) Preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

(b) *Exemption for prescription drugs.* A drug subject to the requirements of section 503 (b) (1) of the act, as amended by 65 Stat. 648, shall be exempt from section 502 (f) (1) if all the following conditions are met:

(1) The drug is:

(i) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or

(ii) In the possession of a retail, hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs;

and is to be dispensed in accordance with section 503 (b), as amended.

(2) The label of the drug bears:

(i) The statement "Caution: Federal law prohibits dispensing without prescription"; and

(ii) The recommended or usual dosage; and

(iii) The route of administration, if it is not for oral use; and

(iv) If it is fabricated from two or more ingredients and is not designated conspicuously by a name recognized in an official compendium, the quantity or proportion of each active ingredient, and if it is not for oral use the names of all other ingredients.

Provided, however, That the information referred to in subdivisions (ii), (iii), and (iv) of this subparagraph may be contained in the labeling on or within the package from which it is to be dispensed, and, in the case of ampuls too small or otherwise unable to accommodate a label but which are packaged in a container from which they are withdrawn for dispensing or use, the information referred to in subdivision (i) of this subparagraph may be placed on the outside container only.

(3) The labeling of the drug (which may include brochures readily available to licensed practitioners) bears information as to the use of the drug by practitioners licensed by law to administer it: *Provided, however,* That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to administer the drug.

(c) *Exemption for veterinary drugs.* A drug intended solely for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502 (f) (1) of the act if all the following conditions are met:

(1) The drug is in the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice.

(2) The label of a drug bears:

(i) The statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian"; and

(ii) The recommended or usual dosage; and

(iii) The route of administration, if it is not for oral use; and

(iv) The quantity or proportion of each active ingredient if it is fabricated from two or more ingredients and is not designated conspicuously by a name recognized in an official compendium.

Provided, however, That the information referred to in subdivisions (ii), (iii), and (iv) of this subparagraph may be contained in the labeling on or within the package from which it is to be dispensed.

(3) The labeling of the drug (which may include brochures readily available to licensed veterinarians) bears information as to use of the drug by licensed veterinarians: *Provided, however,* That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among veterinarians licensed by law to administer such drug.

(d) *Exemption for prescription devices.* A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502 (f) (1) of the act if all the following conditions are met:

(1) The device is in the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device and is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(2) The label of the device (other than surgical instruments) bears:

(i) The statement "Caution: Federal law restricts this device to sale by or on the order of a _____," the blank to be filled with the word "physician," "dentist," "veterinarian," or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(ii) The method of its application or use.

(3) The labeling of the device (which may include brochures readily available to licensed practitioners) bears information as to the use of the device by practitioners licensed by law to use it or direct its use: *Provided, however,* That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to use or order the use of such device.

(e) *Exemptions for drugs and devices shipped directly to licensed practitioners, hospitals, clinics, or public-health agencies for professional use.* Except as provided in paragraph (g) of this section, a drug or device shipped directly to or in the possession of a practitioner licensed by law to administer the drug or to use or direct the use of the device, or shipped directly to or in the possession of a hospital, clinic, or public-health agency, for use in the course of the professional practice of such a licensed practitioner, shall be exempt from section 502 (f) (1) of the act if it meets the conditions of paragraphs (b) (2) and (3), (c) (2) and (3), or (d) (2) and (3) of this section.

(f) *Retail exemption for veterinary drugs and prescription devices.* A drug or device subject to paragraph (c) or (d) of this section shall be exempt at the time of delivery to the ultimate purchaser or user from section 502 (f) (1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

(g) *Exemption for new drugs.* A new drug shall be exempt from section 502 (f) (1) of the act:

(1) To the extent to which such exemption is claimed in an effective application with respect to such drug under section 505 of the act; or

(2) If no application under section 505 of the act is effective with respect to such drug but it complies with section 505 (i) and regulations thereunder.

No exemption shall apply to any other drug which would be a new drug if its labeling bore representations for its intended uses.

(h) *Exemption for drugs or devices when directions are commonly known.* A drug or device shall be exempt from section 502 (f) (1) of the act insofar as adequate directions for common uses thereof are known to the ordinary individual.

(i) *Exemptions for inactive ingredients.* A harmless drug that is ordinarily used as an inactive ingredient, such as a coloring, emulsifier, excipient, flavoring, lubricant, preservative, or solvent, in the preparation of other drugs shall be exempt from section 502 (f) (1) of the act. This exemption shall not apply to any substance intended for a use which results in the preparation of a new drug, unless an effective new-drug application provides for such use.

(j) *Exemption for diagnostic reagents.* A drug intended solely for use in the professional diagnosis of disease and which is generally recognized by qualified experts as useful for that purpose shall be exempt from section 502 (f) (1) of the act if its label bears the statement "Diagnostic reagent—For professional use only."

(k) *Exemption for prescription chemicals and other prescription components.* A drug prepared, packaged, and primarily sold as a prescription chemical or other component for use by registered pharmacists in compounding prescriptions or for dispensing in dosage unit form upon prescriptions shall be exempt from section 502 (f) (1) of the act if all the following conditions are met:

(1) The drug is an official liquid acid or official liquid alkali, or is not a liquid solution, emulsion, suspension, tablet, capsule, or other dosage unit form; and

(2) The label of the drug bears:

(i) The statement "For prescription compounding"; and

(ii) If in substantially all dosage forms in which it may be dispensed it is subject to section 503 (b) (1) of the act, the statement "Caution: Federal law prohibits dispensing without prescription"; or

(iii) If it is not subject to section 503 (b) (1) of the act and is by custom among retail pharmacists sold in or from the interstate package for use by consumers, "adequate directions for use" in the conditions for which it is so sold.

Provided, however, That the information referred to in subdivision (iii) of this subparagraph may be contained in the labeling on or within the package from which it is to be dispensed.

(3) This exemption shall not apply to any substance intended for use in compounding which results in a new drug, unless an effective new-drug application covers such use of the drug in compounding prescriptions.

(l) *Exemption for processing, repacking, or manufacture.* A drug in a bulk package (except tablets, capsules, or other dosage unit forms) or a device intended for processing, repacking, or use in the manufacture of another drug or device shall be exempt from section 502 (f) (1) of the act if its label bears the statement "Caution: For manufacturing, processing, or repacking"; and, if in substantially all dosage forms in which it may be dispensed it is subject to section 503 (b) (1), the statement "Caution: Federal law prohibits dispensing without prescription." This exemption and the exemption under paragraph (k) of this section may be claimed for the same article. But the exemption shall not apply to a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug, unless:

(1) An effective new-drug application held by the person preparing the dosage form or drug for dispensing covers the production and delivery to him of such substance; or

(2) If no application is effective with respect to such new drug, the label statement "Caution: For manufacturing, processing, or repacking" is immediately supplemented by the words "in the preparation of a new drug limited by Federal law to investigational use," and the delivery is made for use only in the manufacture of such new drug limited to investigational use as provided in § 1.114.

(m) *Exemption for drugs and devices for use in teaching, research, and analysis.* A drug or device subject to paragraph (b), (c), or (d) of this section shall be exempt from section 502 (f) (1) of the act if shipped or sold to, or in the

possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, research, analysis, or testing.

(n) *Expiration of exemptions.* (1) If a shipment or delivery, or any part thereof, of a drug or device which is exempt under the regulations in this section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to such shipment or delivery or part thereof, at the beginning of that shipment or delivery. The causing of an exemption to expire shall be considered an act which results in such drug or device being misbranded unless it is disposed of under circumstances in which it ceases to be a drug or device.

(2) The exemptions conferred by paragraphs (i), (j), (k), (l), and (m) of this section shall continue until the drugs or devices are used for the purposes for which they are exempted, or until they are relabeled to comply with section 502 (f) (1) of the act. If, however, the drug is converted, compounded, or manufactured into a dosage form limited to prescription dispensing, no exemption shall thereafter apply to the article unless the dosage form is labeled as required by section 503 (b) and paragraph (b), (c), or (d) of this section.

(o) *Intended uses.* The words "intended uses" or words of similar import in paragraphs (a), (g), (i), (j), (k), and (l) of this section refer to the objective intent of the persons legally responsible for the labeling of drugs and devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug or device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

2. A new § 1.108 is added, to read as follows:

§ 1.108 *Exemption from prescription requirements.* The prescription-dispensing requirements of section 503 (b) (1) (A) of the act are not necessary for the protection of the public health with respect to the following drugs subject to section 502 (d):

(a) Exempt narcotic preparations described in 26 CFR 151.2 and sold as required by 26 CFR 151.180 through 151.185a.

(b) Drugs containing chlorobutanol, intended for external use only.

(c) Epinephrine solution, 1 percent, preserved with chlorobutanol and intended for use solely as a spray.

(d) Drugs containing one or more of the derivatives of barbituric acid and in addition a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of barbiturate derivative to cause a hypnotic or somnifacient effect.

Effective date. These regulations shall be effective upon the date of publication of this final order in the FEDERAL REGISTER except the requirements of § 1.106 (b) (2) (ii), (iii), and (iv), (c) (2), and (k) (2) (iii), which shall be effective on August 1, 1953. Action taken in reliance upon the tentative regulations after April 26, 1952, and before this final order issued will be regarded as in compliance with the law.

(Sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply secs. 502, 503, 52 Stat. 1050, 1051; 21 U. S. C. 352, 353)

Dated: July 22, 1952.

[SEAL] JOHN L. THURSTON,
Acting Administrator.

[F. R. Doc. 52-8156; Filed, July 24, 1952; 8:51 a. m.]

TITLE 26—INTERNAL REVENUE

Chapter I—Bureau of Internal Revenue, Department of the Treasury

Subchapter A—Income and Excess Profits Taxes

[T. D. 5921; Regs. 111]

PART 29—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1941

DEFINITION OF PERSONNEL HOLDING COMPANY; PERSONAL HOLDING COMPANY INCOME

On March 14, 1952, notice of proposed rule making with respect to amendments to conform Regulations 111 to Public Law 680 (81st Cong., 2d Sess.), approved August 9, 1950, relating to definition of personal holding company, and to section 223 of the Revenue Act of 1950 (81st Cong., 2d Sess.), approved September 23, 1950, relating to personal holding company income, was published in the FEDERAL REGISTER (17 F. R. 2231). No objection to the rules proposed having been received, the amendments of Regulations 111 set forth below are hereby adopted.

PARAGRAPH 1. There is inserted immediately preceding § 29.501-1 the following:

PUBLIC LAW 680 (EIGHTY-FIRST CONGRESS, SECOND SESSION), APPROVED AUGUST 9, 1950

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 501 (b) (6) of the Internal Revenue Code is amended to read as follows:

(6) (A) A licensed personal finance company under State supervision, 80 per centum or more of the gross income of which is lawful interest received from loans made to individuals in accordance with the provisions of applicable State law if at least 60 per centum of such gross income is lawful interest (i) received from individuals each of whose indebtedness to such company did not at any time during the taxable year exceed in principal amount the limit prescribed for small loans by such law (or, if there is no such limit, $500), and (ii) not payable in advance or compounded and computed only on unpaid balances, and if the loans to a person, who is a shareholder in such company during the taxable year by or for whom 10 per centum or more in value of its outstanding stock is owned directly or indirectly (including in the case of an individual, stock owned by the members of his family as defined in section 503 (a) (2)), outstanding at any time during such year do not exceed $5,000 in principal amount; and

(B) A lending company, not otherwise excepted by section 501 (b), authorized to engage in the small loan business under one or more State statutes providing for the direct regulation of such business, 80 per centum or more of the gross income of which is lawful interest, discount or other authorized charges (i) received from loans maturing in not more than thirty-six months made to individuals in accordance with the provisions of applicable State law, and (ii) which do not, in the case of any individual loan, exceed in the aggregate an amount equal to simple interest at the rate of 3 per centum per month not payable in advance and computed only on unpaid balances, if at least 60 per centum of the gross income is lawful interest, discount or other authorized charges received from individuals each of whose indebtedness to such company did not at any time during the taxable year exceed in principal amount the limit prescribed for small loans by such law (or, if there is no such limit, $500), and if the deductions allowed to such company under section 23 (a) (relating to expenses), other than for compensation for personal services rendered by shareholders (including members of the shareholder's family as described in section 503 (a) (2)) constitute 16 per centum or more of its gross income, and the loans to a person, who is a shareholder in such company during the taxable year by or for whom 10 per centum or more in value of its outstanding stock is owned directly or indirectly (including in the case of an individual, stock owned by the members of his family as defined in section 503 (a) (2)), outstanding at any time during such year do not exceed $5,000 in principal amount.

SEC. 2. That section 501 (b) of the Internal Revenue Code is amended by adding at the end thereof the following new paragraph:

(8) A finance company, actively and regularly engaged in the business of purchasing or discounting accounts or notes receivable or installment obligations, or making loans secured by any of the foregoing or by tangible personal property, at least 80 per centum of the gross income of which is derived from such business in accordance with the provisions of applicable State law or does not constitute personal holding company income as defined in section 502, if 60 per centum of the gross income is derived from one or more of the following classes of transactions:

(A) Purchasing or discounting accounts or notes receivable, or installment obligations evidenced or secured by contracts of conditional sale, chattel mortgages, or chattel lease agreements, arising out of the sale of goods or services in the course of the transferor's trade or business;

(B) Making loans, maturing in not more than thirty-six months, to, and for the busi-