

350(b)) adjustment is made (to the extent of such liability) by:

(a) Decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937, to which the individual is entitled; or

(b) In the event of the individual's death before adjustment is completed, by decreasing any payment under title II of the Act, or under the Railroad Retirement Act of 1937 payable to the estate of the individual or to any other person, that are based on the individual's earnings record (or compensation).

§ 405.353 Certification of amount that will be adjusted against individual title II or railroad retirement benefits.

As soon as practicable after any adjustment is determined to be necessary, the Secretary, for purposes of this subpart, shall certify the amount of the overpayment or payment (see § 405.350) with respect to which the adjustment is to be made. If the adjustment is to be made by decreasing subsequent payments under the Railroad Retirement Act of 1937, such certification shall be made to the Railroad Retirement Board.

§ 405.355 Waiver of adjustment or recovery.

The provisions of § 405.352, may not be applied and there may be no adjustment or recovery of an overpayment (§ 405.350 (a)) or payment (§ 405.350(b)) in any case where the overpayment has been made with respect to an individual who is without fault, and where such adjustment or recovery would defeat the purpose of title II of the Act, or of the Railroad Retirement Act of 1937, or would be against equity and good conscience.

§ 405.359 Liability of certifying or disbursing officer.

No certifying or disbursing officer shall be held liable for any amount certified or paid by him to any provider of services or other person:

(a) Where the adjustment or recovery of such amount is waived (see § 405.355); or

(b) Where adjustment (see § 405.352) or recovery is not completed prior to the death of all persons against whose benefits such adjustment is authorized.

2. *Effective date.* The addition of Subpart C to Part 405 of Chapter III, Title 20, shall become effective on the date of publication in the FEDERAL REGISTER.

Dated: October 4, 1966.

[SEAL] ROBERT M. BALL,
Commissioner of Social Security.

Approved: October 11, 1966.

WILBUR J. COHEN,
Acting Secretary of Health,
Education, and Welfare.

[F.R. Doc. 66-11423; Filed, Oct. 19, 1966; 8:48 a.m.]

Title 21—FOOD AND DRUGS

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

SUBCHAPTER A—GENERAL

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

Oral Prenatal Drugs Containing Fluorides for Human Use

A number of vitamin-mineral preparations containing fluorides for prenatal use and intended or represented to be beneficial to tooth development in the fetus or in the prevention of dental caries in the offspring have appeared on the market in the last few years. These preparations and any other fluoride-containing drugs offered for the same uses are not generally recognized as effective for these purposes by experts qualified by scientific training and experience to evaluate the effectiveness of drugs.

Accordingly, under the authority vested in the Secretary of Health, Education, and Welfare by the Federal Food, Drug, and Cosmetic Act (secs. 502 (a), (f), 505, 701 (a), 52 Stat. 1050, 1051, 1052, as amended, 1055; 21 U.S.C. 352 (a), (f), 355, 371 (a)) and delegated by him to the Commissioner of Food and Drugs (21 CFR 2.120; 31 F.R. 3008), Part 3 is amended by adding thereto a new statement of policy, as follows:

§ 3.53 Oral prenatal drugs containing fluorides intended for human use.

(a) The Food and Drug Administration finds that there is neither substantial evidence of effectiveness nor a general recognition by qualified experts that prenatal drug preparations containing fluorides are beneficial to tooth development in the fetus or in the prevention of dental caries in the offspring.

(b) Any such drug preparation that is so labeled, represented, or advertised will be regarded as misbranded and subject to regulatory proceedings unless such recommendations are covered by a new-drug application, including substantial evidence of effectiveness, approved pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act.

(c) A completed and signed "Notice of Claimed Investigational Exemption for a New Drug," Form FD-1571 set forth in § 130.3 of this chapter, must be submitted to cover clinical investigations to obtain evidence that such preparations are effective for such uses.

(d) Regulatory proceedings may be initiated with respect to drug preparations labeled contrary to the provisions of this statement and shipped within the jurisdiction of the act after 60 days from the date of publication of this statement in the FEDERAL REGISTER.

(Secs. 502 (a), (f), 505, 701(a); 52 Stat. 1050, 1051, 1052, as amended, 1055; 21 U.S.C. 352 (a), (f), 355, 371 (a))

Dated: October 12, 1966.

JAMES L. GODDARD,
Commissioner of Food and Drugs.

[F.R. Doc. 66-11422; Filed, Oct. 19, 1966; 8:48 a.m.]

Title 22—FOREIGN RELATIONS

Chapter I—Department of State

SUBCHAPTER F—NATIONALITY AND PASSPORTS

[Departmental Reg. 108.541]

REVISION OF SUBCHAPTER

By the authority of Executive Order 11295 and Presidential Proclamation 3004 I hereby revoke the present regulations appearing as Part 50, Nationality Procedures under the Immigration and Nationality Act; Part 51, Passports; Part 52, Births and Marriages; and Part 53, Travel Control of Citizens and Nationals in Time of War or National Emergency. I prescribe the following regulations on these subjects:

PART 50—NATIONALITY PROCEDURES

Sec.

50.1 Definitions.

Subpart A—Procedures for Determination of United States Nationality of a Person Abroad

50.2 Determination of U.S. nationality of persons abroad.

50.3 Application for registration.

50.4 Application for passport.

50.5 Application for registration of birth abroad.

50.6 Registration at the Department of birth abroad.

50.7 Report of birth.

50.8 Certification of birth.

50.9 Certificate of identity and registration.

50.10 Certificate of nationality.

50.11 Certificate of identity for travel to the United States to apply for admission.

Subpart B—Retention and Resumption of Nationality

50.20 Retention of nationality.

50.30 Resumption of nationality.

Subpart C—Loss of Nationality

50.40 Revocation of naturalization under section 340(d).

50.41 Certification of loss of United States nationality.

50.42 Determination of loss of nationality abroad in connection with application for passport in the United States.

50.50 Renunciation of nationality.

50.51 Certification of expatriation.

Subpart D—Board of Review on Loss of Nationality

50.60 Appeal by nationality claimant.

50.61 Organization of the Board of Review on Loss of Nationality.

50.62 Chairman.

50.63 Functions of the Board.

50.64 Scope of review on appeal.