IRMAA determinations based on a beneficiary's income for two out of three successive years. However, because we make determinations annually, a beneficiary will not be subject to an IRMAA in consecutive years unless the MAGI amount used is above the threshold in consecutive years. A one-time increase in MAGI should affect a beneficiary's IRMAA for only one year.

Additionally, the changes made to 20 CFR 418.1210 in the interim final rule help address the scenario discussed by the commenter. In the scenario, an individual received a one-time gain in income due to a forced sale of stock, but experienced a loss of dividend income in subsequent years because of the loss of the stock. The changes we made to 20 CFR 418.1210 clarify that we do not consider events that result in the loss of dividend income to be major life-changing events if the reasons for such loss are due to the ordinary risk of investment. Conversely, a loss of income-producing financial securities, if the circumstances causing the loss are truly beyond a beneficiary's or his or her spouse's control and do not involve the ordinary risk of investment, may qualify as a major life-changing event in the form of a loss of income-producing property under 20 CFR 418.1205(e).

Accordingly, the interim final rule remains unchanged and we are adopting it as final.

Regulatory Procedures

Executive Order 12866 as Supplemented by Executive Order 13563

We have consulted with the Office of Management and Budget (OMB) and determined that this final rule meets the criteria for a significant regulatory action under Executive Order 12866 as supplemented by Executive Order 13563. Thus, the final rule was reviewed by OMB.

Regulatory Flexibility Act

We certify that these final rules will not have a significant economic impact on a substantial number of small entities, because they affect individuals only. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

OMB previously approved the new public reporting requirements posed by this rule under a separate Information Collection Request (OMB No. 0960–0735). We are therefore not seeking OMB approval for these requirements here under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 93.774 Medicare Supplementary Medical Insurance; 96.002 Social Security—Retirement Insurance.)

List of Subjects in 20 CFR Part 418

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping requirements, Supplemental Security Income (SSI), Medicare subsidies.

Michael J. Astrue,

Commissioner of Social Security.

Accordingly, the interim rule amending 20 CFR chapter III, part 418, subpart B that was published at 75 FR 41084 on July 15, 2010, is adopted as a final rule without change.

[FR Doc. 2011–16526 Filed 6–30–11; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2011–N–0003]

Oral Dosage Form New Animal Drugs; Amprolium

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an original abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The ANADA provides for the use of amprolium soluble powder as an aid in the treatment and prevention of coccidiosis in calves.

DATES: This rule is effective July 1, 2011.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200–464 for the use of AMPROMED (amprolium) for Calves, a water-soluble powder used as an aid in the treatment and prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii.* Cross Vetpharm Group Ltd.'s AMPROMED for Calves is approved as a generic copy of Huvepharma AD's CORID (amprolium) 20% Soluble Powder, approved under NADA 33–165. The ANADA is approved as of May 23, 2011, and the regulations in 21 CFR 520.100 are amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. In § 520.100, add paragraph (b)(4) to read as follows:

§ 520.100 Amprolium.

* * * * *

(b) * * *

(4) No. 061623 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

* * * * *

Dated: June 24, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011–16501 Filed 6–30–11; 8:45 am]

BILLING CODE 4160–01–P