

Parameters	Range	Accuracy (sensor input)	Seconds per sampling interval	Resolution	Remarks
12a. Pitch Control(s) position (non-fly-by-wire systems).	Full Range ..	±2° Unless Higher Accuracy Uniquely Required.	0.5 or 0.25 for airplanes operated under § 121.344(f).	0.5% of full range.	For airplanes that have a flight control break away capability that allows either pilot to operate the controls independently, record both control inputs. The control inputs may be sampled alternately once per second to produce the sampling interval of 0.5 or 0.25, as applicable.
19. Pitch Trim Surface Position.	Full Range ..	±3° Unless Higher Accuracy Uniquely Required.	1	0.6% of full range.	

Issued in Washington, DC on July 11, 2005.
Rebecca B. MacPherson,
Assistant Chief Counsel for Regulations.
 [FR Doc. 05-14036 Filed 7-15-05; 8:45 am]
BILLING CODE 4910-13-P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 416

RIN 0960-AE79

Technical Revisions to the Supplemental Security Income (SSI) Regulations on Income and Resources

AGENCY: Social Security Administration (SSA).

ACTION: Final rules.

SUMMARY: We are amending our SSI regulations by making technical revisions to our rules on income and resources based on the Social Security Protection Act (SSPA) of 2004 and several other statutory changes. These technical revisions update lists of exclusions from income and resources under the SSI program and make additional technical corrections.

DATES: These regulations are effective July 18, 2005.

FOR FURTHER INFORMATION CONTACT: Eric Ice, Social Insurance Specialist, Social Security Administration, Office of Income Security Programs, 252 Altmeyer Building, 6401 Security Boulevard, Baltimore, MD 21235-6401, (410) 966-3233 or TTY 1-800-966-5906 for information about this notice. For information on eligibility or filing for benefits, call our national toll-free numbers, 1-800-772-1213 or TTY 1-800-325-0778, or visit our Internet site, Social Security Online, at <http://www.socialsecurity.gov>.

Electronic Version

The electronic file of this document is available on the date of publication in

the **Federal Register** at <http://www.gpoaccess.gov/fr/index.html>.

SUPPLEMENTARY INFORMATION:

Background

The basic purpose of the SSI program (title XVI of the Social Security Act (the Act)) is to ensure a minimum level of income to people who are age 65 or older, or blind or disabled, and who have limited income and resources. The law provides that payments can be made only to people who have income and resources below specified amounts. Therefore, the income and resources a person has are major factors in deciding whether the person is eligible to receive SSI benefits and in computing the amount of benefits.

Regulations for the SSI program are in title 20, chapter III, part 416 of the Code of Federal Regulations. In part 416, subpart K contains our regulations on income and subpart L contains our regulations on resources.

Explanation of Revisions

In these final rules we are making minor revisions and technical changes to the SSI regulations in part 416. We are making technical corrections and adding a paragraph to one section in subpart K to reflect legislative changes, and updating the appendix to subpart K which lists exclusions from income in statutes other than the Act. We also are revising subpart L by adding a new section and making several technical revisions based on the SSPA of 2004, Public Law 108-203, that was enacted on March 2, 2004, by updating the list of statutory exclusions from resources based on statutes other than the Act, and by adding a new section to reflect another legislative change.

Revisions to Subpart K—Income

1. We are revising § 416.1124(c) to update the list of types of unearned income that we do not count to

determine eligibility or benefit amount for the SSI program as follows:

- In paragraph (c)(2), a reference is made to the Aid to Families with Dependent Children (AFDC) program. The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub. L. 104-193) effectively replaced the AFDC program with the Temporary Assistance for Needy Families (TANF) program. We are updating paragraph (c)(2) to reflect this legislative change.

- We are adding paragraph (c)(21) to § 416.1124 to reflect section 7 of the Noncitizen Benefit Clarification and Other Technical Amendments Act of 1998 (Pub. L. 105-306) which amended the Act by adding section 1612(b)(22). Section 1612(b)(22) of the Act excludes from income gifts given by certain tax exempt organizations to children who have a life-threatening condition. New paragraph (c)(21) will exclude from income, gifts that are given to, or for the benefit of an individual who has not attained 18 years of age and who has a life-threatening condition. To be excluded from income, these gifts must be given by an organization as described in section 501(c)(3) of the Internal Revenue Code of 1986 which is exempt from taxation under section 501(a) of such Code. The types of gifts that will be excluded are any in-kind gift that is not converted to cash, and cash gifts to the extent that the total gifts do not exceed \$2000 in any calendar year. In-kind gifts converted to cash are considered under income counting rules in the month of conversion.

2. We are also revising § 416.1142(a)(1) to replace the reference to “Aid to Families with Dependent Children” with “Temporary Assistance for Needy Families”.

Revisions to Appendix to Subpart K— Income Excluded by Federal Laws Other Than the Act

At the end of part 416, subpart K, we maintain an appendix which lists types of income excluded under the SSI program as provided by Federal laws other than the Act. We update this list periodically. However, we apply the law in effect due to changes in Federal statutes whether or not the list in the appendix has been amended to reflect the statutory changes. We are revising the appendix to subpart K as follows:

1. Under the heading “IV. NATIVE AMERICANS,” we are adding the following two new paragraphs:

- Paragraph (b)(37) excludes judgment funds distributed under section 111 of the Michigan Indian Land Claims Settlement Act, (Pub. L. 105–143, 111 Stat. 2665) from income.
- Paragraph (b)(38) excludes judgment funds distributed under section 4 of the Cowlitz Indian Tribe Distribution of Judgment Funds Act, (Pub. L. 108–222, 118 Stat. 624) from income.

2. Under the heading “V. OTHER,” we are revising paragraph (a) to exclude from income compensation provided to volunteers by the Corporation for National and Community Service (CNCS), unless they are determined by the CNCS to constitute the minimum wage in effect under the Fair Labor Standards Act of 1938 (29 U.S.C. 201 *et seq.*), or applicable State law, pursuant to 42 U.S.C. 5044(f)(1). This revision is being made pursuant to the National and Community Service Trust Act of 1993, (Pub. L. 103–82) which established the CNCS by combining two formerly independent agencies: ACTION and the Commission on National and Community Service.

3. Under the heading “V. OTHER,” we are also adding five new paragraphs setting forth income exclusions as follows:

- Paragraph (h) excludes any matching funds and any interest earned on matching funds in an Individual Development Account (IDA), as provided for by section 415 of the Community Opportunities, Accountability, and Training and Educational Services Act of 1998 (Pub. L. 105–285). These IDAs are funded by a demonstration project authorized by Public Law 105–285.
- Paragraph (i) excludes any earnings, TANF matching funds, and interest in an IDA, as provided for by section 103 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub. L. 104–193, 42 U.S.C. 604(h)(4)).
- Paragraph (j) excludes payments made to individuals who were captured

and interned by the Democratic Republic of Vietnam as a result of participation in certain military operations, as provided for by section 606 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriation Act of 1996 (Pub. L. 105–78).

- Paragraph (k) excludes payments made to certain Vietnam veterans’ children with spina bifida, pursuant to section 421 of the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act of 1997 (Pub. L. 104–204, 38 U.S.C. 1805(d)).
- Paragraph (l) excludes payments made to the children of women Vietnam veterans who suffer from certain birth defects, pursuant to section 401 of the Veterans Benefits and Health Care Improvement Act of 2000 (Pub. L. 106–419; 38 U.S.C. 1833(c)).

Revisions to Subpart L—Resources and Exclusions

1. We are revising §§ 416.1203 and 416.1204, which outline our rules for deeming of resources of essential persons, and alien sponsors, respectively. These revisions are necessary because section 101 of Public Law 108–203 requires that we exclude from counting as a resource for 9 months following the month of receipt restitution of title II, title VIII and title XVI benefits made because of misuse by certain representative payees. In addition to excluding funds paid as restitution to an individual (or spouse), we must also exclude from resources for 9 months following the month of receipt restitution paid to any other person whose income is considered to be income of the individual (or spouse) for SSI purposes. We use the term “deeming” to identify the process of considering another person’s income and resources to be the individual’s own income and resources.

2. We are revising § 416.1210, which lists resource exclusions in the SSI program. Specifically, we are adding a new paragraph (s) to reflect section 7 of Public Law 105–306 which excludes gifts to children with life-threatening conditions. Additionally, we are adding a new paragraph (t) to reflect the provision of section 101 of Public Law 108–203 that excludes from resources for 9 months restitution received for benefits misused by certain representative payees.

3. We are revising § 416.1233, which outlines the exclusion of certain title II and title XVI underpayments from resources under the SSI program. Specifically, we are revising paragraph (a) because section 431 of Public Law

108–203 increased from 6 months to 9 months the time period for excluding from resources any unspent portion of retroactive title II and title XVI benefits.

4. We are revising § 416.1235, which outlines the exclusion of the earned income tax credit (EITC) from resources under the SSI program. This revision is necessary because section 431 of Public Law 108–203 increased from one to 9 months, following the month of receipt, the time period for excluding from resources any unspent portion of Federal income taxes related to an EITC.

5. We are revising § 416.1236, which lists certain exclusions from resources under the SSI program which are required by other Federal statutes. Specifically, we are revising § 416.1236(a)(9) to exclude from resources payments made to volunteers by CNCS, unless determined by CNCS to constitute the minimum wage in effect under the Fair Labor Standards Act of 1938 (29 U.S.C. 201 *et seq.*), or applicable State law, pursuant to 42 U.S.C. 5044(f)(1). This revision is being made pursuant to Public Law 103–82 which established the CNCS by combining two formerly independent agencies: ACTION and the Commission on National and Community Service.

6. We are adding six new paragraphs to § 416.1236(a) which set forth resource exclusions as follows.

- Paragraph (19) excludes any matching funds from a demonstration project authorized by Public Law 105–285 and any interest earned on these matching funds that are retained in an IDA, as provided for by section 415 of Public Law 105–285.
- Paragraph (20) excludes any earnings, TANF matching funds, and accrued interest retained in an IDA, pursuant to section 103 of Public Law 104–193, 42 U.S.C. 604(h)(4).
- Paragraph (21) excludes payments made to individuals who were captured and interned by the Democratic Republic of Vietnam as a result of participation in certain military operations, as provided for by section 606 of Public Law 105–78.
- Paragraph (22) excludes payments made to certain Vietnam veterans’ children with spina bifida, pursuant to section 421 of Public Law 104–204, 38 U.S.C. 1805(d).
- Paragraph (23) excludes payments made to the children of women Vietnam veterans who suffer from certain birth defects, pursuant to section 401 of Public Law 106–419, 38 U.S.C. 1833(c).
- Paragraph (24) excludes for the 9 months following the month of receipt, any unspent portion of any refund of Federal income taxes under section 24 of the Internal Revenue Code of 1986

(relating to the child care tax credit), pursuant to section 431 of Public Law 108–203.

7. We are adding a new § 416.1248 to reflect section 7 of Public Law 105–306 which amended the Act by adding section 1613(a)(13). Section 1613(a)(13) of the Act excludes from resources gifts given by certain tax exempt organizations to children who have a life-threatening condition. Section 416.1248 will exclude from resources gifts that are given to, or for the benefit of, an individual who has not attained 18 years of age and who has a life-threatening condition. To be excluded from resources, these gifts must be given by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 which is exempt from taxation under section 510(a) of such Code. The types of gifts that will be excluded are any in-kind gift that is not converted to cash, and cash gifts to the extent that the total gifts do not exceed \$2000 in any calendar year. In-kind gifts converted to cash are considered under income counting rules in the month of conversion.

8. Finally, we are adding § 416.1249 to reflect section 101 of Public Law 108–203, the SSPA of 2004, which amended the Act by adding section 1613(a)(14). Prior to the SSPA of 2004, we counted restitution for benefits misused by a representative payee as a resource in the month following the month of receipt. Section 101 of the SSPA provides that any amount received as restitution for title II, title VIII or title XVI benefits misused by a representative payee is excluded from counting as a resource for 9 months following the month of receipt. The exclusion applies to any case of benefit misuse by a representative payee with respect to which the Commissioner makes a determination of misuse on or after January 1, 1995.

Regulatory Procedures

Justification for Final Rule

Pursuant to section 702(a)(5) of the Act, 42 U.S.C. 902(a)(5), as amended by section 102 of Public Law 103–296, SSA follows the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 in the development of its regulations. The APA provides exceptions to its notice of proposed rulemaking (NPRM) and public comment procedures when an agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that, under 5 U.S.C. 553(b)(B), good cause

exists for dispensing with the NPRM and public comment procedures in this case. Good cause exists because these rules contain only changes that reflect current statutory exclusions of income and resources and make two minor technical changes, none of which involve the discretionary setting of policy. Therefore, opportunity for prior comment is unnecessary, and we are issuing these changes to our regulations as final rules.

In addition, we find good cause for dispensing with the 30-day delay in the effective date of a substantive rule provided by 5 U.S.C. 553(d). As explained above, we are merely implementing non-discretionary changes, minor revisions, and technical changes based on statutory enactments.

Executive Order 12866

The Office of Management and Budget (OMB) has reviewed these final rules. We have also determined that these final rules meet the plain language requirement of Executive Order 12866, as amended by Executive Order 13258.

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 only individuals. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These final rules impose no reporting or recordkeeping requirements subject to OMB clearance.

(Catalog of Federal Domestic Assistance Program No. 96.006, Supplemental Security Income.)

List of Subjects in 20 CFR Part 416

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

Dated: April 12, 2005.

Jo Anne B. Barnhart,
Commissioner of Social Security.

■ For the reasons set out in the preamble, we are amending subpart K, the appendix of subpart K, and subpart L of part 416 of chapter III of title 20 of the Code of Federal Regulations as follows:

PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart K—[Amended]

■ 1. The authority citation for subpart K of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1602, 1611, 1612, 1613, 1614(f), 1621, and 1631 of the Social Security Act (42 U.S.C. 902(a)(5), 1381a, 1382, 1382a, 1382b, 1382c(f), 1382j, and 1383); sec. 211, Pub. L. 93–66, 87 Stat. 154 (42 U.S.C. 1382 note).

■ 2. Section 416.1124 is amended by revising the last sentence of paragraph (c)(2), by removing the word “and” at the end of paragraph (c)(19), by removing the period at the end of paragraph (c)(20) and adding a semicolon in its place followed by the word “and”, and by adding paragraph (c)(21) to read as follows:

§ 416.1124 Unearned income we do not count.

* * * * *

(c) * * *

(2) * * * Assistance based on need includes State supplementation of Federal SSI benefits as defined in subpart T of this part but does not include payments under a Federal/State grant program such as Temporary Assistance for Needy Families under title IV–A of the Social Security Act;

* * * * *

(21) Gifts from an organization as described in section 501(c)(3) of the Internal Revenue Code of 1986 which is exempt from taxation under section 501(a) of such Code, to, or for the benefit of, an individual who has not attained 18 years of age and who has a life-threatening condition. We will exclude any in-kind gift that is not converted to cash and cash gifts to the extent that the total gifts excluded pursuant to this paragraph do not exceed \$2000 in any calendar year. In-kind gifts converted to cash are considered under income counting rules in the month of conversion.

■ 3. Section 416.1142 is amended by revising paragraph (a)(1) to read as follows:

§ 416.1142 If you live in a public assistance household.

(a) * * *

(1) Title IV–A of the Social Security Act (Temporary Assistance for Needy Families);

* * * * *

■ 4. The appendix to subpart K of part 416 is amended by adding new paragraphs (b)(37) and (b)(38) under Part IV, and by revising paragraph (a) (the note following paragraph (a) remains unchanged) and adding new paragraphs

(h), (i), (j), (k) and (l) under Part V to read as follows:

Appendix to Subpart K of Part 416— [Amended]

* * * * *

IV. Native Americans

* * * * *

(b) * * *

(37) Judgment funds distributed under section 111 of the Michigan Indian Land Claims Settlement Act, (Pub. L. 105-143, 111 Stat. 2665).

(38) Judgment funds distributed under section 4 of the Cowlitz Indian Tribe Distribution of Judgment Funds Act, (Pub. L. 108-222, 118 Stat. 624).

* * * * *

V. Other

(a) Compensation provided to volunteers by the Corporation for National and Community Service (CNCS), unless determined by the CNCS to constitute the minimum wage in effect under the Fair Labor Standards Act of 1938 (29 U.S.C. 201 et seq.), or applicable State law, pursuant to 42 U.S.C. 5044(f)(1).

* * * * *

(h) Any matching funds from a demonstration project authorized by the Community Opportunities, Accountability, and Training and Educational Services Act of 1998 (Pub. L. 105-285) and any interest earned on these matching funds in an Individual Development Account, pursuant to section 415 of Pub. L. 105-285 (112 Stat. 2771).

(i) Any earnings, Temporary Assistance for Needy Families matching funds, and interest in an Individual Development Account, pursuant to section 103 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Pub. L. 104-193, 42 U.S.C. 604(h)(4)).

(j) Payments made to individuals who were captured and interned by the Democratic Republic of Vietnam as a result of participation in certain military operations, pursuant to section 606 of the Departments of Labor, Health and Human Services and Education and Related Agencies Appropriations Act of 1996 (Pub. L. 105-78).

(k) Payments made to certain Vietnam veterans' children with spina bifida, pursuant to section 421 of the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act of 1997 (Pub. L. 104-204, 38 U.S.C. 1805(a)).

(l) Payments made to the children of women Vietnam veterans who suffer from certain birth defects, pursuant to section 401 of the Veterans Benefits and Health Care Improvement Act of 2000 (Pub. L. 106-419 (38 U.S.C. 1833(c)).

Subpart L—[Amended]

■ 5. The authority citation for subpart L of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1602, 1611, 1612, 1613, 1614(f), 1621, and 1631 of the Social Security Act (42 U.S.C. 902(a)(5),

1381a, 1382, 1382a, 1382b, 1382c(f), 1382j, and 1383); sec. 211, Pub. L. 93-66, 87 Stat. 154 (42 U.S.C. 1382 note).

■ 6. Section 416.1203 is amended by revising the first sentence to read as follows:

§ 416.1203 Deeming of resources of an essential person.

In the case of a qualified individual (as defined in § 416.221) whose payment standard has been increased because of the presence of an essential person (as defined in § 416.222), the resources of such qualified individual shall be deemed to include all the resources of such essential person with the exception of the resources explained in § 416.1210(t) and § 416.1249. * * *

■ 7. Section 416.1204 is amended by revising the second sentence in paragraph (a) to read as follows:

§ 416.1204 Deeming of resources of the sponsor of an alien.

* * * * *

(a) Exclusions from the sponsor's resources. * * * The applicable exclusions from resources are explained in § 416.1210 (paragraphs (a) through (i), (k), and (m) through (t)) through § 416.1239 and § 416.1247 through § 416.1249. * * *

* * * * *

■ 8. Section 416.1210 is amended by removing the word "and" at the end of paragraph (q), by removing the period at the end of paragraph (r) and adding a semicolon in its place, and by adding paragraphs (s) and (t) to read as follows:

§ 416.1210 Exclusion from resources; general.

* * * * *

(s) Gifts to children under age 18 with life-threatening conditions as provided in § 416.1248; and

(t) Restitution of title II, title VIII or title XVI benefits because of misuse by certain representative payees as provided in § 416.1249.

■ 9. Section 416.1233 is amended by revising paragraph (a) to read as follows:

§ 416.1233 Exclusion of certain underpayments from resources.

(a) General. In determining the resources of an eligible individual (and spouse, if any), we will exclude, for 9 months following the month of receipt, the unspent portion of any title II or title XVI retroactive payment received on or after March 2, 2004. Exception: We will exclude for 6 months following the month of receipt the unspent portion of any title II or title XVI retroactive payment received before March 2, 2004. This exclusion also applies to such

payments received by any other person whose resources are subject to deeming under this subpart.

* * * * *

■ 10. Section 416.1235 is revised to read as follows:

§ 416.1235 Exclusion of earned income tax credit.

In determining the resources of an individual (and spouse, if any), we exclude for the 9 months following the month of receipt the unspent portion of any refund of Federal income taxes under section 32 of the Internal Revenue Code (relating to earned income tax credit) and the unspent portion of any payment from an employer under section 3507 of the Internal Revenue Code (relating to advance payment of earned income tax credit). This exclusion applies to such refunds and such payments received on or after March 2, 2004. Any unspent funds retained until the first moment of the tenth month following their receipt are subject to resource counting at that time. Exception: We will exclude for the month following the month of receipt the unspent portion of any refund of Federal income taxes under section 32 of the Internal Revenue Code (relating to earned income tax credit) and the unspent portion of any payment from an employer under section 3507 of the Internal Revenue Code (relating to advance payment of earned income tax credit) received before March 2, 2004.

■ 11. Section 416.1236 is amended by revising paragraph (a)(9) and adding new paragraphs (a)(19) through (a)(24) to read as follows:

§ 416.1236 Exclusions from resources; provided by other statutes.

(a) * * *

(9) Compensation provided to volunteers by the Corporation for National and Community Service (CNCS), unless determined by the CNCS to constitute the minimum wage in effect under the Fair Labor Standards Act of 1938 (29 U.S.C. 201 et seq.), or applicable State law, pursuant to 42 U.S.C. 5044(f)(1).

* * * * *

(19) Any matching funds and interest earned on matching funds from a demonstration project authorized by Public Law 105-285 that are retained in an Individual Development Account, pursuant to section 415 of Public Law 105-285 (112 Stat. 2771).

(20) Any earnings, Temporary Assistance for Needy Families matching funds, and accrued interest retained in an Individual Development Account, pursuant to section 103 of Public Law 104-193 (42 U.S.C. 604(h)(4)).

(21) Payments made to individuals who were captured and interned by the Democratic Republic of Vietnam as a result of participation in certain military operations, pursuant to section 606 of Public Law 105-78 and section 657 of Public Law 104-201 (110 Stat. 2584).

(22) Payments made to certain Vietnam veterans' children with spina bifida, pursuant to section 421 of Public Law 104-204 (38 U.S.C. 1805(d)).

(23) Payments made to the children of women Vietnam veterans who suffer from certain birth defects, pursuant to section 401 of Public Law 106-419, (38 U.S.C. 1833(c)).

(24) For the 9 months following the month of receipt, any unspent portion of any refund of Federal income taxes under section 24 of the Internal Revenue Code of 1986 (relating to the child care tax credit), pursuant to section 431 of Public Law 108-203 (118 Stat. 539).

■ 12. Section 416.1248 is added to read as follows:

§ 416.1248 Exclusion of gifts to children with life-threatening conditions.

In determining the resources of an individual who has not attained 18 years of age and who has a life-threatening condition, we will exclude any gifts from an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 which is exempt from taxation under section 501(a) of such Code. We will exclude any in-kind gift that is not converted to cash and cash gifts to the extent that the total gifts excluded pursuant to this paragraph do not exceed \$2000 in any calendar year. In-kind gifts converted to cash are considered under income counting rules in the month of conversion.

■ 13. Section 416.1249 is added to read as follows:

§ 416.1249 Exclusion of payments received as restitution for misuse of benefits by a representative payee.

In determining the resources of an individual (and spouse, if any), the unspent portion of any payment received by the individual as restitution for title II, title VIII or title XVI benefits misused by a representative payee under § 404.2041, § 408.641 or § 416.641, respectively, is excluded for 9 months following the month of receipt.

[FR Doc. 05-14050 Filed 7-15-05; 8:45 am]

BILLING CODE 4191-02-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 529

Certain Other Dosage Form New Animal Drugs; Oxytetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for use of oxytetracycline hydrochloride soluble powder for skeletal marking of finfish fry and fingerlings by immersion. **DATES:** This rule is effective July 18, 2005.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.gov.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed a supplement to NADA 8-622 that provides for use of TERRAMYCIN-343 (oxytetracycline HCl) Soluble Powder for skeletal marking of finfish fry and fingerlings by immersion. The approval of this supplemental NADA relied on publicly available safety and effectiveness data contained in Public Master File (PMF) 5667 which were compiled under National Research Support Project-7 (NRSP-7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses. In addition, the supplemental NADA provides for the addition of statements to product labeling warning against the use of this product in drinking water of lactating dairy cattle. The supplemental NADA is approved as of June 13, 2005, and the regulations in 21 CFR 529.1660 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA has found that the regulations contain incorrect statements warning against the use of oxytetracycline soluble powder in calves intended for veal. Accordingly, the regulations in 21 CFR 520.1660d are amended to reflect appropriate warning statements for this product. This action is being taken to improve the accuracy of the regulations.

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(d)(4) 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 Parts 520 and 529

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 parts 520 and 529 are 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. Section 520.1660d is amended by revising paragraph (d)(1)(iv)(C) to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

* * * * *

(d) * * *

(1) * * *

(iv) * * *

(C) *Limitations.* Prepare a fresh solution daily. Administer up to 14 days. Do not use for more than 14 consecutive days. Use as sole source of oxytetracycline. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Withdraw 5 days prior to slaughter. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

* * * * *