§ 95.8003 VOR	FEDERAL AIRWAY CHANGEOVER POINTS		
Airway	Segment	Changeov	er Points
From	То	Distance	From
IV-184 is	Amended to Delete Changeover Point		
Cedar Lake, NJ VORTAC	Atlantic City, NJ VORTAC	10	Cedar Lake
V-319 is	Amended to Add Changeover Point		
Sparrevohn, AK VOR/DME	Bethel, AK VORTAC	92	Sparrevohn
V-440 is	Amended to Add Changeover Point		
Unalakleet AK VORTAC	Nome, AK VORTAC	80	Unalakleet

[FR Doc. 99–9303 Filed 4–14–99; 8:45 am] BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Customs Service

[T.D. 99-40]

19 CFR Part 122

Withdrawal of International Airport Designation of Akron Fulton Airport

AGENCY: U.S. Customs Service, Department of the Treasury. **ACTION:** Final rule.

SUMMARY: This document amends the Customs Regulations pertaining to the field organization of the Customs Service by withdrawing the international airport designation of Akron Municipal Airport (now functioning as Akron Fulton Airport) and by designating Akron Fulton Airport as a landing rights airport instead. The change is made as part of Customs continuing program to obtain more efficient use of its personnel, facilities and resources, and to provide better service to carriers, importers and the general public.

EFFECTIVE DATE: May 17, 1999. FOR FURTHER INFORMATION CONTACT: Betsy Passuth, Office of Field Operations, 202–927–0795. SUPPLEMENTARY INFORMATION:

Background

As part of a continuing program to obtain more efficient use of its personnel, facilities and resources and to provide better service to carriers, importers and the general public, Customs proposed to withdraw the international airport designation of Akron Municipal Airport (now functioning as Akron Fulton Airport) and to designate Akron Fulton Airport as a landing rights airport instead. A

Notice of Proposed Rulemaking to this effect was published in the **Federal Register** (63 FR 11383) on March 9, 1998. The designation as an international airport was proposed to be withdrawn because of lack of sufficient international travel through the airport and because of failure of the airport operator to maintain an adequate facility.

Determination

No comments either supporting or opposing the proposal were received. After further consideration of the proposal, Customs has determined to proceed with withdrawing the international airport designation of Akron Fulton Airport and to designate the airport as a landing rights airport instead. The Customs inspectors stationed adjacent to the Akron-Canton Regional Airport will be able to provide Customs services to international aircraft at the Akron Fulton Airport on an as-needed basis.

Regulatory Flexibility Act and Executive Order 12866

Customs establishes, expands, consolidates and makes other changes to Customs ports of entry throughout the United States to accommodate the volume of Customs-related activity in various parts of the country. Although a notice on this subject matter requesting public comment was issued, the subject matter is not subject to the notice and public procedure requirements of 5 U.S.C. 553 because it relates to agency management and organization. Accordingly, this final rule is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). Agency organization matters such as this are exempt from Executive Order 12866.

Drafting Information. The principal author of this document was Janet L. Johnson, Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 122

Air carriers, Aircraft, Airports, Air transportation, Customs duties and inspection, Freight, Imports, Organization and functions (Government agencies).

Amendment to the Regulations

Accordingly, Part 122 of the Customs Regulations is amended as set forth below.

PART 122—AIR COMMERCE REGULATIONS

1. The authority citation for part 122 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 58b, 66, 1433, 1436, 1448, 1459, 1590, 1594, 1623, 1624, 1644, 1644a.

§122.13 [Amended]

2. The list of international airports in § 122.13 is amended by removing the entry "Akron, Ohio—Akron Municipal Airport".

Raymond W. Kelly,

Commissioner of Customs.

Approved: March 12, 1999.

John P. Simpson,

Deputy Assistant Secretary of the Treasury. [FR Doc. 99–9345 Filed 4–14–99; 8:45 am] BILLING CODE 4820–02–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Regulations No. 4 and 16] RIN 0960-AE98

Old-Age, Survivors, and Disability Insurance and Supplemental Security Income for the Aged, Blind, and Disabled; Substantial Gainful Activity Amounts

AGENCY: Social Security Administration.

ACTION: Final rules.

SUMMARY: We are revising the rules for determining when earnings demonstrate the ability to engage in substantial gainful activity (SGA). This rule change applies to Social Security disability benefits provided under title II of the Social Security Act (the Act) and Supplemental Security Income (SSI) benefits based on disability under title XVI of the Act. (Eligibility for benefits under titles II and XVI also confers eligibility for related Medicare and Medicaid benefits under titles XVIII and XIX of the Act.) Specifically, we are raising from \$500 to \$700 the average monthly earnings guidelines used to determine whether work done by persons with impairments other than blindness is SGA. We are raising this level as part of efforts to encourage individuals with disabilities to attempt to work, and to provide an updated indicator of when earnings demonstrate the ability to engage in SGA. This increase reflects our assessment of the amount that roughly corresponds to wage growth since the last increase in 1990.

EFFECTIVE DATE: These rules are effective July 1, 1999.

FOR FURTHER INFORMATION CONTACT: Jack Baumel, Office of Employment Support Programs, Social Security
Administration, 6401 Security
Boulevard, Baltimore, Maryland 21235–6401, (410) 965–9834 or TTY (410) 966–6210. For information about eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet web site, SSA Online, www.ssa.gov.

SUPPLEMENTARY INFORMATION:

Background

Under 20 CFR 404.1572 and 416.972, the term "substantial gainful activity" means work activity that involves significant physical or mental effort and that is done for pay or profit. Work activity is gainful if it is the kind of work usually performed for pay or profit, whether or not a profit is realized. Sections 223(d)(4)(A) and 1614(a)(3)(E) of the Act require the Commissioner to prescribe by regulations the criteria for determining when earnings demonstrate ability to engage in SGA for a person with an impairment other than blindness.

The amount of average monthly earnings that ordinarily demonstrates SGA for people with an impairment other than blindness has not been increased since January 1, 1990. We are revising this level now after reassessing

the current guidelines as part of our effort to improve incentives to encourage individuals with disabilities to attempt to work. We believe that the increase in the amount of earnings that constitutes SGA provides an updated indicator of when earnings demonstrate the ability to engage in SGA and is a significant improvement to the existing work incentive provisions.

Proposed Rules

We published a notice of proposed rulemaking (NPRM) in the Federal Register on February 16, 1999 (64 FR 7559). In the NPRM, we proposed rules to increase the amount in the monthly earnings guidelines used in determining whether the work activities of a person with an impairment other than blindness demonstrate that he or she is able to perform SGA. These guidelines in §§ 404.1574 and 416.974 deal with persons claiming title II or title XVI benefits or receiving title II benefits based on disability. Under our prior rules, if such a person had earnings from work activities as an employee (including as an employee of a sheltered workshop or comparable facility) that averaged more than \$500 a month, we would ordinarily consider that the person had engaged in SGA. Under these new rules, the \$500 amount is raised to \$700 per month.

While these rules make specific increases to the amount of earnings that will ordinarily show that a person has engaged in SGA, we will, at a future point, consider making other changes in the work incentive rules. Therefore, the NPRM invited the public to provide us with general suggestions for changes which might be desirable in related provisions (such as the trial work period services amount, and the earnings level that ordinarily demonstrates that an individual has not engaged in SGA) and the SGA guidelines in the future. We will consider those general suggestions not addressed below regarding possible future changes.

Public Comments

We received over 3000 sets of comments in response to the proposal. Commenters included many advocates for people with disabilities, State and local government entities, attorneys, employees from one SSA field office, one Administrative Law Judge, one member of Congress, and a large number of private citizens. With few exceptions, the comments we received were substantive assessments of the proposal and/or related suggestions. We have summarized these substantive comments, grouped them by subject, and discuss them below.

Comment: All but five of the comments received expressing an opinion about the proposed increase in the SGA guidelines were in favor. One was opposed and four expressed doubt that the increase in the SGA guidelines would achieve improvement. Many of the commenters in favor also believed that we should make further changes.

Response: We appreciate that all but a few commenters agreed with our assessment that an increase in the SGA guidelines is warranted. We have addressed the additional comments below.

Comment: Many of the comments expressing support for an increase also stated the general opinion that the proposed increase to \$700 was not enough. Several commenters suggested that geographic differences in the costof-living or poverty level be taken into account in setting the SGA amount. Many expressed the view that the \$700 amount is below the amount SGA would have attained had its growth kept pace with increases in average wages since its inception. Many also noted that the new \$700 amount is significantly lower than a month's full-time earnings at the minimum wage level. Many also criticized us regarding the nine years lapse since the last increase.

Response: The historical relationship between the SGA amount and average wage growth was roughly consistent between 1961 (when the SGA guideline was first issued by regulation) and 1980. Since 1980, however, the SGA level has been kept constant for two long periods of time during which wages were experiencing growth. By 1989, the actual SGA level for the non-blind lagged behind average wage growth since the amount had stayed at \$300 for a decade. In 1990, we raised the SGA amount to \$500.

The Act does not spell out the definition of SGA for people with impairments other than blindness and the legislative record neither expresses nor implies a connection with average wages or prices. The Act provides that the Commissioner is to prescribe by regulation the criteria for determining when earnings demonstrate the ability to engage in SGA. We designed the SGA guidelines as a way of measuring an individual's ability to work and not as a measure of an individual's need for income. We decided on the amounts being implemented based on our experience with the disability programs and beneficiaries' work efforts and the need to maintain fiscal responsibility. In any event, the increase we are implementing now approximately corresponds to wage growth since 1990.

Comment: Many comments noted that the SGA amount for people who are blind is \$1110 for calendar year 1999. These comments expressed dissatisfaction with the discrepancy and generally considered it unjustified discrimination. Most of these commenters recommended that we increase the SGA amount for people with impairments other than blindness in a similar manner or to the same level as for people who are blind.

Response: Before 1977, Section 223(d) of the Act authorized the Commissioner to prescribe the level of earnings that demonstrate SGA for all title II applicants and recipients and all title XVI applicants. In 1977, Congress amended that section of the Act to provide a different criterion for setting the SGA level for people who are blind (i.e., annual adjustment based on the national average wage index). Congress consciously made this distinction between people who are blind and those with impairments other than blindness. The House and Senate conference report accompanying the Social Security Amendments of 1977 clearly stated that a different SGA amount was being established for blind persons, and that the conferees did not intend that the amount be applied to people with impairments other than blindness.

Comment: Many comments suggested either annual review of the SGA amount or that future increases be linked to increases in a generally recognized economic benchmark, e.g., average wage, cost-of-living, poverty level. They contend that annual review or indexing the SGA level would provide a consistent relationship with wages and/or prices, and prevent erosion of the work component of the definition of disability over time as these factors increase.

Response: As stated in a previous response, we designed the SGA guidelines as a way of measuring an individual's ability to work and not as a measure of an individual's need for income. We decided on the amounts we are implementing based on our experience with the disability programs and beneficiaries' work efforts and the need to maintain fiscal responsibility. The increase we are implementing now approximately corresponds to wage growth since 1990. However, we recognize that increasing program factors on a regular and predictable basis allows us to avoid making adjustments on an ad hoc basis. We may consider, in the future, if the SGA amounts should be indexed.

Comment: Several comments suggested that we stop using SGA to evaluate the work component of

disability. They recommended that, in its place, we use an earnings offset formula to reduce cash benefits gradually as earnings rise (similar to the earned income exclusion currently under title XVI). One suggested that there should be no earnings limits placed on eligibility for people with disabilities.

Response: These suggested changes require new legislation and we can not implement them by regulation alone. Several legislative proposals to test the earnings offset approach under title II are pending before the current session of Congress.

Comment: Many commenters suggested that we also increase the monthly earnings amount that we consider being services for purposes of the Trial Work Period (TWP). Many of these also suggested that the TWP and SGA amounts should be the same. Many of these also suggested that we index TWP increases to an economic benchmark. One suggested that we apply the TWP earnings amount on an annual basis rather than monthly.

Response: The TWP is a work incentive. During the TWP, a title II beneficiary may test his or her ability to work and still be considered disabled. We will not consider services performed during the TWP as showing that disability has ended until services have been performed in at least 9 months (not necessarily consecutive). Services means any activity, even though it is not SGA, which is done by a person in employment or self-employment for pay or profit, or is the kind normally done for pay or profit. As established in § 404.1592(b), if you are an employee, we currently consider your work to be services if you earn more than \$200 a month. As a result of public comments, we will consider whether, in the future, to propose raising the monthly earnings guideline for services under the trial work period and related changes.

Comment: One commenter recommended raising the average monthly earnings amount that will ordinarily show that an employee did NOT engage in SGA (currently, earnings of less than \$300).

Response: The effect of this provision is to create a range where monthly earnings are neither high enough nor low enough to show whether an employee engaged in SGA. If an employee's earnings fall into this range, we generally consider other information in addition to the employee's earnings to reach a determination. In practice, this provision affects a relatively small number of people. As a result of public comments, we will consider whether, in the future, to propose raising the

amount and/or make other modification(s) to this provision.

Comment: Many comments expressed general support for the recognition of the special medical needs and medical insurance needs of people with disabilities. Several comments expressed support for recognition of the special needs of young people with disabilities who are in transition from education to work. Several comments advocated liberalization of other existing work incentive provisions and included suggestions for changes to these provisions.

Response: The issues addressed by these comments are outside the scope of this specific rules change. However, as we stated in the February 16, 1999 NPRM, we will consider these comments regarding possible future changes.

Comment: A few commenters suggested that a January 1, 1999 effective date for the SGA increase would be easier for us to administer and seem less arbitrary to the public.

Response: This rules change increases the number of people eligible for disability benefits under Old-Age, Survivors and Disability Insurance and the SSI program, as well as for related Medicare and Medicaid benefits. We believe it is in the public interest to proceed quickly with its implementation. However, we believe that an effective date of July 1, 1999 represents the earliest date practicable for these final rules to be effective.

Final Regulations

We are revising §§ 404.1574(b)(2) and (4), and 416.974(b)(2) and (4) to increase from \$500 to \$700 the earnings guidelines that we use to determine whether a non-blind employee is engaging in SGA. (This standard also applies to the self-employed in certain circumstances by cross-references that have been and continue to be present in §§ 404.1575 and 416.975.) We have not raised the SGA earnings amount for approximately nine years. We are raising the SGA level now to \$700, which roughly corresponds to wage growth since the last increase in 1990.

In order to comply with the President's June 1, 1998 memorandum directing the use of plain language for all proposed and final rulemaking, we are rewriting the regulatory paragraphs affected by the above rule changes and the intervening paragraph ((b)(3)) into plain language. We intend this rewrite to have no substantive effect other than those substantive changes described in this preamble to these final rules.

Electronic Version

The electronic file of this document is available on the Internet at www.access.gpo.gov/nara. This document is also available on our Internet web site, SSA Online, www.ssa.gov.

Regulatory Procedures

Paperwork Reduction Act

These regulations impose no new reporting/record-keeping requirements necessitating clearance by the Office of Management and Budget (OMB).

Executive Order 12866

Regulatory Impact Analysis

Introduction—Based on the costs associated with these final rules, the Social Security Administration has determined that they require an assessment of costs and benefits to society per Executive Order 12866 because they meet the definition of a "significant regulatory action." These final rules also meet the definition of a "major rule" under 5 U.S.C. 801ff., and this assessment also fulfills the requirements of those provisions as well. In addition, SSA has determined, as required under the aforementioned statute, that these final rules do not create any unfunded mandates for State or local entities pursuant to sections 202-205 of the Unfunded Mandates Act of 1995. OMB has reviewed these final rules.

Executive Order 12866 includes in its definition of a "significant regulatory action" one which generates a major increase in costs for the Federal government. Accordingly, a discussion follows of the effect of the regulations and general information on estimated costs and benefits to society.

Nature of the Program—Benefits to disabled and blind individuals are provided under title II and title XVI of the Act. Disability is defined under both programs as, "* * * inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment * * *." Related medical benefits to disabled and blind individuals are provided under title XVIII and title XIX of the Act.

We use earnings guidelines to evaluate a person's work activity to determine whether the work activity is SGA and therefore whether that person may be considered disabled under the law. While this is only one of the tests used to determine disability, it is a critical threshold in disability evaluation. We evaluate the work activity of persons claiming or receiving disability benefits under title II of the Act and that of persons claiming benefits because of a disability under title XVI of the Act. These new regulations increase the amounts of those earnings guidelines. We have not raised the SGA earnings amount for approximately nine years. We are raising it now to approximate wage growth during that time.

Intended Effect—We expect that the increase in the amount of earnings that constitute SGA will provide a greater incentive for many people with disabilities to attempt to work or, if already working, to continue to work or increase their work effort. Hundreds of thousands of people with disabilities already work and the new revisions will be of advantage to many. For these individuals, as well as those not now working, the new revisions will enhance their potential to participate in the workforce, and, consequently, improve their economic well being by increasing their income through earnings.

In addition, the increase will permit some individuals with disabilities who have earnings in excess of the prior regulatory limit (\$500) but less than the amount in these new rules (\$700), to receive benefits. We estimate that by Fiscal Year (FY) 2004, an additional 27,000 individuals will receive benefits because of these changes. This estimate is based on analyses of the earnings distributions of a representative sample of disabled individuals.

The following chart provides the estimated increases in Old-age, Survivors and Disability Insurance payments, Federal SSI payments, Medicare benefits, and Federal share of Medicaid benefits due to the increase in the SGA amount to \$700 in 1999, for fiscal years 1999–2004. (Amounts are in millions.)

	Fiscal year			Total			
	1999	2000	2001	2002	2003	2004	1999–2004
OASDI	10 15 10 40	30 20 20 60	55 25 30 70	75 25 50 75	100 30 60 90	120 30 80 100	390 145 250 435
Subtotal, all programs	75	130	180	225	280	330	1220

Notes:

¹ Totals may not equal sum of rounded components.

² Above estimates based on the assumptions underlying the President's FY 2000 Budget, including the SSA Office of the Actuary's normal assumption of an SGA amount increasing with average wages.

³ Estimates for Medicare and Medicaid provided by the Office of the Actuary in the Health Care Financing Administration (HCFA).

In addition, since States share in the costs of financing Medicaid, States will

have some costs associated with the increase in the SGA amount as well.

These costs are estimated by HCFA to be (in millions):

Fiscal year Medicaid					Total		
Medicald	1999	2000	2001	2002	2003	2004	1999–2004
State Share	30	45	55	55	70	75	330

Although the costs are significant, we consider these changes as necessary improvements to the work incentives. The costs of these regulations will be

paid through programmatic and regulatory changes.

Regulatory Flexibility Act

We certify that these regulations do not have a significant economic impact

on a substantial number of small entities because they primarily affect individuals who are applying for or receiving title II, or applying for title XVI, benefits because of disability, and States which administer the Medicaid program.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

Administrative practice and procedure, Death benefits, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and record keeping requirements, Social Security.

20 CFR Part 416

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

Dated: April 7, 1999.

Kenneth S. Apfel,

Commissioner of Social Security.

For the reasons stated in the preamble, the Social Security Administration is amending parts 404 and 416 of chapter III of title 20 of the Code of Federal Regulations as follows:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205 (a), (b), and (d)–(h), 216(i), 221 (a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405 (a), (b), and (d)–(h), 416(i), 421 (a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

2. Section 404.1574 is amended by revising paragraphs (b)(2), (b)(3), and (b)(4) to read as follows:

§ 404.1574 Evaluation guides if you are an employee.

(b) * * *

(2) Earnings that will ordinarily show that you have engaged in substantial gainful activity. We will consider that your earnings from your work activity as an employee show that you have engaged in substantial gainful activity if—

For months	Your month- ly earnings averaged more than
In calendar years before 1976 In calendar year 1976 In calendar year 1977 In calendar year 1978 In calendar year 1979 In calendar years 1980—1989 In January 1990—June 1999 After June 1999	\$200 230 240 260 280 300 500

(3) Earnings that will ordinarily show that you have not engaged in substantial gainful activity. We will generally consider that the earnings from your work as an employee will show that you have not engaged in substantial gainful activity if—

For months	Your month- ly earnings averaged more than
In calendar years before 1976 In calendar year 1976 In calendar year 1977 In calendar year 1978 In calendar year 1979 In calendar years 1980–1989 After December 1989	\$130 150 160 170 180 190 300

(4) If you work in a sheltered workshop. If you are working in a sheltered workshop or a comparable facility especially set up for severely impaired persons, your earnings and activities will ordinarily establish that you have not done substantial gainful activity if—

For months	Your average monthly earnings are not greater than
In calendar years before 1976	\$200
In calendar year 1976	230
In calendar year 1977	240
In calendar year 1978	260
In calendar year 1979	280
In calendar years 1980-1989	300
In January 1990-June 1999	500
After June 1999	700

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

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

Authority: Secs. 702(a)(5), 1611, 1614, 1619, 1631(a), (c) and (d)(1), and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c) and (d)(1), and 1383b); secs. 4(c) and 5, 6(c)–(e), 14(a) and 15, Pub. L. 98–460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, 1382h note).

2. Section 416.974 is amended by revising paragraphs (b)(2), (b)(3), and (b)(4) to read as follows:

§ 416.974 Evaluation guides if you are an employee.

* * * * * (b) * * *

(2) Earnings that will ordinarily show that you have engaged in substantial gainful activity. We will consider that your earnings from your work activity as an employee show that you have engaged in substantial gainful activity if—

For months	Your month- ly earnings averaged more than
In calendar years before 1976 In calendar year 1976 In calendar year 1977 In calendar year 1978 In calendar year 1979 In calendar year 1980—1989 In January 1990—June 1999 After June 1999	\$200 230 240 260 280 300 500 700

(3) Earnings that will ordinarily show that you have not engaged in substantial gainful activity. We will generally consider that the earnings from your work as an employee will show that you have not engaged in substantial gainful activity if—

For months	Your month- ly earnings averaged less than
In calendar years before 1976 In calendar year 1976 In calendar year 1977 In calendar year 1978 In calendar year 1979 In calendar years 1980—1989 After December 1989	\$130 150 160 170 180 190

(4) If you work in a sheltered workshop. If you are working in a sheltered workshop or a comparable facility especially set up for severely impaired persons, your earnings and activities will ordinarily establish that you have not done substantial gainful activity if—

For months	Your month- ly earnings averaged more than
In calendar years before 1976 In calendar year 1976 In calendar year 1977 In calendar year 1978 In calendar year 1979 In calendar years 1980–1989 In January 1990–June 1999 After June 1999	\$200 230 240 260 280 300 500 700

[FR Doc. 99-9427 Filed 4-14-99; 8:45 am] BILLING CODE 4190-29-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 330, 331, 341, 346, 355, 358, 369, and 701

[Docket Nos. 98N-0337, 96N-0420, 95N-0259, and 90P-0201]

RIN 0910-AA79

Over-The-Counter Human Drugs; Labeling Requirements; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the Federal Register of March 17, 1999 (64 FR 13254). The final rule established a standardized format and standardized content requirements for the labeling of over-the-counter (OTC) drug products. The document was inadvertently published with an incorrect effective date. This document corrects that error.

DATES: Effective April 15, 1999, the effective date of the final rule published on March 17, 1999 (64 FR 13254) is corrected to May 16, 1999.

FOR FURTHER INFORMATION CONTACT:

Debra L. Bowen, Food and Drug Administration, Center for Drug Evaluation and Research (HFD-560), 5600 Fishers Lane, Rockville, MD 20852, 301-827-2222, or email "BOWEND@cder.fda.gov".

SUPPLEMENTARY INFORMATION: In FR Doc. 99-6296, appearing on page 13254 in the **Federal Register** of Wednesday, March 17, 1999, the following correction is made:

1. On page 13254, in the first column, under the "Dates" section "Effective Date: April 16, 1999." is corrected to read "Effective Date: May 16, 1999."

Dated: April 12, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy. [FR Doc. 99-9520 Filed 4-14-99; 8:45 am] BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; **Dichlorvos Tablets**

AGENCY: Food and Drug Administration,

ACTION: Final rule.

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 Boehringer Ingelheim Vetmedica, Inc. The supplemental NADA provides for veterinary prescription use of additional dichlorvos tablet sizes for the treatment of certain worm infections in cats and puppies and for the treatment of dogs and kittens.

EFFECTIVE DATE: April 15, 1999.

FOR FURTHER INFORMATION CONTACT:

Dennis M. Bensley, Center for Veterinary Medicine (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956.

SUPPLEMENTARY INFORMATION:

Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506–2002, is the sponsor of NADA 48-271 that provides for veterinary prescription use of Task® (dichlorvos) tablets for cats and puppies for removal and control of certain intestinal roundworms and hookworms. The firm filed a supplemental NADA that provides for the use of 10- and 20milligram (mg) dichlorvos tablets, in addition to 2- and 5-mg tablets, in cats and puppies, and for the use of dichlorvos tablets in dogs and kittens. The supplemental NADA is approved as of March 4, 1999, and the regulations are amended by revising 21 CFR 520.600(i) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, the list of sponsors of approved applications in 21 CFR 510.600(c) is amended to reflect the sponsor's current zip code.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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.

The agency has determined under 21 CFR $25.\overline{33}$ (d)(1) 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.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§510.600 [Amended]

2. Section 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications is amended in the table in paragraph (c)(1) in the entry for "Boehringer Ingelheim Vetmedica, Inc." and in the table in paragraph (c)(2) in the entry for "000010" by removing "64502" and adding in its place "64506-2002".

PART 520—ORAL DOSAGE FORM **NEW ANIMAL DRUGS**

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

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

4. Section 520.600 is amended by revising paragraph (i) to read as follows:

§520.600 Dichlorvos.

- (i) Conditions of use in dogs, cats, puppies, and kittens. (1) Each tablet contains 2, 5, 10, or 20 milligrams of dichlorvos.
- (2) It is administered orally at 5 milligrams of dichlorvos per pound of body weight.
- (3) Dogs and puppies: Removal and control of intestinal roundworms (Toxocara canis and Toxascaris leonina) and hookworms (Ancylostoma caninum and Uncinaria stenocephala).
- (4) Cats and kittens: Removal and control of intestinal roundworms