

Disorders." The body system listing name was changed in the final rule published on December 12, 1990 (55 FR 51208), but the name was not corrected in this list.

Regulatory Procedures

Pursuant to section 702(a)(5) of the Social Security 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 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 notice and public comment procedures in this case. Good cause exists because this regulation only extends the dates on which these body system listings will no longer be effective and makes two related nonsubstantive technical changes. It makes no substantive changes to the listings. The current regulations expressly provide that the listings may be extended, as well as revised and promulgated again. Therefore, opportunity for prior comment is unnecessary, and we are issuing this regulation as a final rule.

In addition, we find good cause for dispensing with the 30-day delay in the effective date of a substantive rule, provided for by 5 U.S.C. 553(d). As explained above, we are not making any substantive changes in these body system listings. However, without an extension of the expiration dates for these listings, we will lack regulatory guidelines for assessing impairments in these body systems at the third step of the sequential evaluation processes after the current expiration dates of the listings. In order to ensure that we continue to have regulatory criteria for assessing these impairments under the listings, we find that it is in the public interest to make this rule effective upon publication.

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that this rule does not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, it was not subject to OMB review.

Regulatory Flexibility Act

We certify that this regulation will not have a significant economic impact on

a substantial number of small entities. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

This regulation imposes no reporting/recording requirements necessitating clearance by OMB.

(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 in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: May 29, 1997.

John J. Callahan,

Acting Commissioner of Social Security.

For the reasons set forth in the preamble, part 404, subpart P, chapter III of title 20 of the Code of Federal Regulations is amended as set forth below.

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

Subpart P—[Amended]

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. Appendix 1 to subpart P is amended by removing item 14 of the introductory text before part A, renumbering items 15 and 16 as items 14 and 15, and revising items 2, 6 through 10, 13, and the renumbered item 14 to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

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2. Musculoskeletal System (1.00 and 101.00): June 7, 1999.

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6. Digestive System (5.00 and 105.00): December 6, 1999.

7. Genito-Urinary System (6.00 and 106.00): December 6, 1999.

8. Hemis and Lymphatic System (7.00 and 107.00): June 7, 1999.

9. Skin (8.00): June 7, 1999.

10. Endocrine System and Obesity (9.00) and Endocrine System (109.00): June 7, 1999.

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13. Mental Disorders (12.00 and 112.00): August 27, 1999.

14. Neoplastic Diseases, Malignant (13.00 and 113.00): June 7, 1999.

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3. Part A of Appendix 1 to subpart P is amended by removing the introductory paragraph of 12.00 Mental Disorders.

4. Part B of Appendix 1 to subpart P is amended by revising the entry for 112.00 in the list at the beginning of part B to read as follows:

* * * * *

§ 112.00 Mental Disorders

* * * * *

[FR Doc. 97–14613 Filed 6–4–97; 8:45 am]

BILLING CODE 4190–29–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 416

[Regulations No. 16]

RIN 0960–AD65

Supplemental Security Income for the Aged, Blind, and Disabled; Reliable Information Which Is Currently Available for Determining Benefit Amounts in the Supplemental Security Income Program

AGENCY: Social Security Administration (SSA).

ACTION: Final rules.

SUMMARY: The Social Security Act (the Act) provides that if the Commissioner of Social Security determines that reliable information is currently available concerning the income of an individual, the Commissioner may use that information to determine an individual's current month's supplemental security income (SSI) benefit amount. This method of determining SSI benefit amounts is an exception to the use of income from a prior month, known as retrospective monthly accounting (RMA). These rules provide that the Commissioner, in exercising his or her discretionary authority, has determined that no reliable information exists which is currently available for determining SSI benefit amounts for a current month using any method other than RMA. **EFFECTIVE DATE:** These rules are effective July 7, 1997.

FOR FURTHER INFORMATION CONTACT: Henry D. Lerner, Legal Assistant, Division of Regulations and Rulings, Social Security Administration, 6401 Security Blvd., Baltimore, MD 21235, (410) 965–1762 for information about

these rules. For information on eligibility or claiming benefits, call our national toll-free number, 1-800-772-1213.

SUPPLEMENTARY INFORMATION: In accordance with the orders of the United States District Court for the Central District of California in the case of *Newman, et al. v. Shalala*, No. CV 89-04028 SVW (October 20, 1993), and the United States Court of Appeals for the Ninth Circuit in *Newman v. Chater*, 87 F.3d 358 (1996), we are providing rules concerning reliable information for determining benefits in the SSI program pursuant to section 1611(c)(4) of the Act. A different district court, in *Gould v. Sullivan*, 819 F. Supp. 685 (S.D. Ohio 1992), ordered us to propose a rule concerning section 1611(c)(4) of the Act. On March 16, 1993, we published a notice of proposed rulemaking (NPRM) in the **Federal Register** (58 FR 14191) with a correction notice published in the **Federal Register** (58 FR 26383) on May 3, 1993. The NPRM provided 60 days in which the public could comment on the proposed rules. The district court in *Newman* also ordered us to propose a rule concerning section 1611(c)(4) with a 60-day comment period. The *Newman* district court found that the NPRM we published in March 1993 complied with this aspect of the order. Further, the *Newman* district court directed us to publish in the **Federal Register** a final rule concerning 1611(c)(4). In these cases, the Commissioner had argued that unless he identified reliable information which is currently available and which he intended to use as an exception to the usual RMA rules, the publication of regulations is not necessary. This position was upheld on July 27, 1994 by the United States Court of Appeals for the Sixth Circuit in *Gould v. Shalala*, 30 F.3d 714 (1994) when the district court's decision was reversed. The circuit court agreed that the publication of regulations is not necessary under section 1611(c)(4) of the Act. However, on June 25, 1996, the United States Court of Appeals for the Ninth Circuit in *Newman v. Chater*, 87 F.3d 358 (1996), affirmed the district court decision directing us to publish a final rule in the **Federal Register**. In light of the directive in *Newman* to publish a final rule, we are publishing these rules explaining that we have determined that no reliable information exists for determining SSI benefits. The NPRM which was published pursuant to the district court's decision in *Gould* provided 60 days in which the public could comment on the proposed rules. That period has run, and we have

received public comments to which we will now respond.

Previously, we published final regulations on November 26, 1985 (50 FR 48563), implementing various provisions in section 1611(c) of the Act. Section 1611(c)(1) of the Act, the RMA provision, provides that an individual's eligibility for SSI benefits is to be determined based on income, resources, and other relevant characteristics from the current month. The SSI benefit amount for a month is to be determined on the basis of income and other characteristics in the first or, if the Commissioner so chooses, the second month preceding the month of eligibility. The final regulations provided that generally the income and other characteristics in the second month preceding the month of eligibility are to be used for determining the amount of SSI benefits.

Section 1611(c)(3) of the Act provides that an increase in Social Security (title II) benefits over the amount payable for the first preceding month, or at the Commissioner's election, the second preceding month, will be counted in determining the amount of an SSI benefit for the first month or, at the Commissioner's election, the second month in which there is an SSI benefit increase due to a cost-of-living adjustment (COLA) made under section 1617 of the Act. The final regulations, published November 26, 1985 (50 FR 48563), provided for counting an increase from a COLA or recomputation in Social Security benefits for January and February as income in the month received to determine the SSI benefit amounts for January and February.

Section 1611(c)(4)(A) of the Act provides that if the Commissioner determines, at his or her discretion, that reliable information is currently available about an individual's income and other circumstances for a month, the Commissioner, at his or her discretion, may determine the SSI benefit amount for that month on the basis of that information rather than based on income and other characteristics from the first or second prior month as required under RMA pursuant to section 1611(c)(1) of the Act. This is known as the "reliable information exception" to the RMA provision. If the Commissioner determines that reliable information is currently available and he or she further determines that he or she may use it to affect the current SSI benefit amount, section 1611(c)(4)(B) requires the Commissioner to issue regulations prescribing the circumstances in which the information may be used to determine the SSI benefit amount.

However, under section 1611(c)(4), the Commissioner, at his or her discretion, may continue to use RMA even if he or she identifies reliable information which is currently available.

With respect to recipients, the optional computation under section 1611(c)(4)(A) of the Act would, in comparison to RMA, be advantageous in some circumstances and disadvantageous in others. Consider, for illustrative purposes only, what would happen if the Commissioner were to determine that all title II income information is reliable and currently available and is to be used to determine the current month's benefit.

Title II income above \$20 serves to reduce the SSI benefit dollar-for-dollar. A reduction in the ongoing title II benefit amount will result in an increase in the SSI benefit, and, conversely, an increase in the title II benefit will result in a reduction in the SSI benefit. Under RMA, the effects of changes in title II income other than COLA or recomputation increases are generally delayed 2 months. For example, an SSI recipient who is receiving title II mother's benefits and whose benefits terminate because she no longer has a child in her care would continue to receive a reduced SSI benefit for 2 months after the termination of the title II income. Conversely, an SSI recipient who becomes entitled to a title II mother's benefit will continue to receive an unreduced SSI benefit for 2 months after the title II benefit begins, and her SSI benefit would not be reduced until the third month following title II entitlement.

Under the current month accounting approach, title II income would affect the SSI benefit as of the month the income is received. The mother whose title II benefit terminates would receive increased SSI in the month following termination. The SSI recipient who subsequently becomes entitled to a title II benefit would have her SSI benefit reduced effective with the month she begins receiving the title II benefit.

Statistically valid sample data indicate that using current month accounting for title II income would be disadvantageous to more SSI recipients than it would be advantageous. Of the approximately 99,400 recipients whose title II income started or stopped in the 12 months ending with June 1996 and who continued to receive SSI benefits, 78.3 percent would have received less in total SSI benefits under current month accounting and 21.7 percent would have received more. Of the approximately 131,000 recipients whose countable title II income increased or decreased in those 12 months and who

continued to receive SSI benefits, 71.3 percent would have received less in total SSI benefits using current month accounting, while 28.7 percent would have received more.

For purposes of RMA, we are defining "reliable information" in these final regulations as payment information maintained on a computer system of records by the government agency determining the payments (e.g., Department of Veterans Affairs, the Office of Personnel Management for Federal civil service information, and the Railroad Retirement Board). Because this is actual payment information which is verified by the custodial agency, it is correct virtually all the time. We define the term "currently available information" as information that is available to the Commissioner within the time required for us to compute and issue a correct SSI benefit for the month the information is pertinent.

When we published the regulations on November 26, 1985 (50 FR 48563), to reflect various provisions of section 1611(c) of the Act, we discussed the section 1611(c)(4) exception (50 FR 48565) using the following language:

These regulations do not include a rule to determine a current month's benefit based on reliable information which is currently available. The Secretary has this matter under consideration, and is not exercising this authority at this time.

After publication of the final rules, we examined information regarding other Federal and State benefit programs to determine whether these sources could provide us reliable information which is currently available to be used for determining SSI benefit amounts. The following explains what we determined as a result of this examination.

We maintain computer interfaces only with some Federal agencies, such as the Department of Veterans Affairs, the Office of Personnel Management for Federal civil service information, and the Railroad Retirement Board. We receive this benefit information through computer interface after these other agencies prepare their payment tapes for the Treasury Department to use in issuing benefit checks or making electronic deposits. These interfaces provide us with information with respect to income and other circumstances. We use this information to maintain and update the SSI records for eligible individuals.

The Privacy Act, 5 U.S.C. 552a(p), requires that if the computer match data would cause SSA to take an adverse action against an individual (i.e., to reduce, suspend, terminate or deny

payments), SSA must notify the individual of our findings, including the data and their source, and defer the adverse action until the expiration of any time period established for the program by statute or regulation for the individual to respond to the notice (10 days in the SSI program) to give the individual the opportunity to challenge the accuracy of the data. Because of the time required for the receipt of the data and individual notification and appeal rights, data we receive from these other agencies in January, for example, cannot adversely affect an individual's payment until March at the earliest. Thus, based on our definition, we cannot consider even timely computer interface information from other agencies to be currently available for determining the SSI benefit amount.

In addition to the computer interfaces with other agencies, we maintain a computer interface with title II records within SSA. The title II interface does not require special electronic matching and is not subject to the Privacy Act requirements discussed above. Pursuant to sections 1611(c)(2) and 1611(c)(3), we determine the SSI benefit amount for a month based on certain income received in that month.

However, our regulations provide, based on *Goldberg versus Kelly*, 397 U.S. 254 (1970), that before SSA can reduce, suspend or terminate an SSI payment, we must issue a written notice to the individual informing him or her of the event and providing the opportunity to appeal. If an adverse change is posted on an SSI claimant's record after the 10th day of the month, due to computer system constraints, we are unable to reduce the SSI payment for the next month. This creates an overpayment for the individual. Because of the advance notice requirements and systems limitations, only changes posted to the SSI record by the 10th of the month before the payment month affect the payment. Because of the various increases and decreases in title II benefits occurring throughout the month, approximately one-half of the changes are posted by the 10th of the month before the payment month. For the other one-half of the cases involving changes, the information is not currently available for SSA's system to make timely changes in order to avoid causing an overpayment or an underpayment. It would be inequitable to treat title II income differently in the computation of an SSI payment based on when in the month the income was received because such differing treatment could lead to different SSI benefit amounts for two individuals

with identical title II income in a particular month.

Based on the foregoing review and examination of computer interface information, the Commissioner has determined that no information exists which is reliable and currently available to use in computing SSI benefit amounts pursuant to section 1611(c)(4). Therefore, the regulations explain that the Commissioner is exercising his or her discretion by declining to determine the SSI benefit amount for a current month using a method other than RMA, as allowed under section 1611(c)(4) of the Act.

We are amending § 416.420 to define the terms "reliable information" and "currently available information" and to state that the Commissioner has determined that there exists no reliable information which is currently available to use for determining SSI benefit amounts under section 1611(c)(4).

As noted above, these regulations were published in the **Federal Register** (58 FR 14191) on March 16, 1993, as an NPRM with a correction notice published in the **Federal Register** (58 FR 26383) on May 3, 1993. Interested individuals were given 60 days to submit comments. Comments were received from three attorneys in response to the NPRM.

Discussion of Comments

A summary of the comments and our responses follow. For ease of reference, we have grouped the comments according to the issues raised.

Comment: Two commenters disagreed with our definition of reliable, which limits reliable information to benefit payment information maintained on a computer-based system of records by the government agency determining the payments. One commenter stated that in other areas we make determinations based on information provided by the recipients. Another commenter stated that SSA should have conducted studies to compare the accuracy of data received by electronic tapes, telephone, or paper.

Response: These commenters ignore the crucial distinction between the way information is used under normal RMA processing and the way its use is contemplated under this exception to RMA. Under RMA, SSA generally has two months' lead time to verify and process reported changes in income, including information provided by recipients and claimants *before* such changes affect the payment. We are required to verify this information by section 1631(e) of the Act. Under the exception which provides for current month accounting, such changes would

affect the payment immediately, with no opportunity for prior verification. Therefore, application of more stringent criteria to ensure the reliability of that information is appropriate.

Because the data would be applied immediately to the computation of benefit amounts without additional verification, necessary components of "reliability" are that the data be obtained from the original source agency and that it be obtained in such a way that the Commissioner can be confident that no alteration has taken place. Also, given the number of SSI recipients for which we must calculate benefit amounts monthly, and the potential for frequent fluctuation of benefit payment information, a computerized system of information is the most accurate, accessible and efficient system for purposes of large numbers of calculations. These considerations buttress the definition of "reliable" contained in the NPRM and demonstrate its reasonable, not arbitrary, nature.

Comment: Two commenters stated that our definition of "currently available" is flawed because it ignores the "reality" of how benefit computations are made. The commenters correctly note that many SSI benefit computations, particularly those which result from a recent application for SSI, are made for payment months in the past as well as current payment months. Therefore, the commenters state, reliable information is currently available, and should be used, when these retroactive benefit calculations are made.

Response: Were we to adopt this approach, we would then have two different sets of computation rules depending upon whether we were computing current or retroactive payments. Consequently, it would be possible for two individuals with identical income in the same months to be due different benefit amounts, depending on when their payments were calculated. Such an approach would be inequitable.

Comment: Addressing specifically the question of AFDC income (which was processed under RMA rules from 1982 until April 1988, at which time Congress, under section 9106 of Pub. L. 100-203, specifically mandated current month accounting for this income), one commenter states "... the Commissioner is aware that the AFDC income ceases as a matter of law when the recipient becomes eligible for SSI."

Response: Local procedures developed in various States and counties to meet local needs and conditions govern the interactions of

local SSA field offices and the State AFDC agency in communicating when SSI is to begin and AFDC is to terminate. The State AFDC agency must tell SSA when the AFDC terminates. This may be accomplished via written or telephone communication. This is not a fail-safe process, and periodic reminder items have been issued to field offices when we become aware of errors. Therefore, we believe that this information does not fit our definition of "reliable" or "currently available" for purposes of a procedure of current month accounting that would rely upon fast, accurate transmission of data.

Comment: One commenter asserts that the proposed rule is inconsistent with SSA's other practices, that the terms "reliable" and "currently available" are not used elsewhere in the regulations, and that we have used an unreasonably constricted sense of the concepts which the terms represent.

Response: Because section 1611(c)(4) provides an exception to the usual method of calculating SSI benefit amounts, the terminology is unique to that provision. Therefore, these terms would not be used in our regulations other than in a regulation concerning the section 1611(c)(4) exception to RMA. We do not find an inconsistency between the proposed rule and SSA's other practices as the reliable information exception to RMA is not addressed elsewhere in our regulations. Finally, for the reasons we explained in responses to comments discussed previously, we do not believe we have used an unreasonably constricted sense of the concepts of "reliable" and "current available" information.

Comment: One commenter also questions why, if current month accounting is not possible, the Commissioner does not implement one-month retrospective accounting under section 1611(c)(4).

Response: The Commissioner has discretion to use one-month retrospective accounting under section 1611(c)(1) and would not need to implement section 1611(c)(4) to do so.

Comment: One commenter discusses the statistical data presented in the proposed rule as it pertains to the reliable information exception. The commenter states that this information was not produced during the course of litigation, including cases in Ohio and California, regarding section 1611(c)(4).

Response: While the statistical data was not requested by any of the plaintiffs in the various lawsuits, it was presented by the Government in the *Newman* case. Moreover, this statistical data is relevant to the regulations process. The data in the proposed rule,

as well as the updated data in these final rules, indicates the treatment of title II income information as an exception to RMA would be disadvantageous to more SSI recipients than it would be advantageous. Under RMA, changes in the SSI benefit due to changes in countable income are delayed for two months (except for cost-of-living increases). It is far more likely that an SSI recipient will begin receiving, or have an increase in, his or her Social Security benefit (and consequently would receive an advantage under RMA rather than under current month accounting), than it is that his or her Social Security benefit will terminate or be reduced.

Comment: One commenter states that SSA, by not implementing this exception to RMA, is missing an opportunity to improve the accounting system's responsiveness to current need.

Response: Congress' intent in instituting RMA was to reduce the number of incorrect payments which were being made under the previous method of quarterly prospective accounting. RMA allows for income changes that are reported promptly to be taken into account in determining subsequent payments rather than requiring SSI benefit amounts to be determined on the basis of income anticipated by the recipient in the payment month under a current month accounting method. Because the current month's payment is computed based on income from two months ago, if that income changes there is obviously a lag in adjustment of the SSI benefit to the new income level, but this benefit calculation process generally is less prone to error. If Congress had intended instantaneous benefit adjustments in any substantial manner rather than as a limited discretionary exception, Congress would have enacted current month accounting.

For the reasons discussed above, we are adopting these rules essentially as proposed.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these rules do not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, they are not subject to OMB review.

Paperwork Reduction Act

These regulations impose no new reporting or recordkeeping requirements subject to OMB clearance.

Regulatory Flexibility Act

We certify that these rules will not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis as provided in Pub. L. 96-354, the Regulatory Flexibility Act, is not required.

(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: May 27, 1997.

John J. Callahan,

Acting Commissioner of Social Security.

Subpart D of part 416 of chapter III of title 20 of the Code of Federal Regulations is amended as follows:

PART 416—[AMENDED]

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

Authority: Secs. 702(a)(5), 1611(a), (b), (c), and (e), 1612, 1617, and 1631 of the Social Security Act (42 U.S.C. 902(a)(5), 1382(a), (b), (c), and (e), 1382a, 1382f, and 1383).

2. Section 416.420 is amended by revising paragraph (a) and redesignating paragraph (c) as paragraph (d) and adding a new paragraph (c) to read as follows:

§ 416.420 Determination of benefits; general.

* * * * *

(a) *General rule.* We use the amount of your countable income in the second month prior to the current month to determine how much your benefit amount will be for the current month. We have determined that no reliable information exists which is currently available to compute benefits on a current basis as is explained in paragraph (c) of this section. However, if you have been receiving an SSI benefit and receiving a Social Security insurance benefit and the latter is increased on the basis of the cost-of-living adjustment or because your benefit is recomputed, we will compute the amount of your SSI benefit for January, the month of an SSI benefit increase, by including in your income the amount by which your Social Security benefit in January exceeds the amount of your Social Security benefit in November. Similarly, we will compute the amount of your SSI benefit for February by including in your

income the amount by which your Social Security benefit in February exceeds the amount of your Social Security benefit in December.

Example 1. Mrs. X's benefit amount is being determined for September (the current month). Mrs. X's countable income in July is used to determine the benefit amount for September.

Example 2. Mr. Y's SSI benefit amount is being determined for January (the current month). Mr. Y has Social Security income of \$100 in November, \$100 in December, and \$105 in January. We find the amount by which his Social Security income in January exceeds his Social Security income in November (\$5) and add that to his income in November to determine the SSI benefit amount for January.

* * * * *

(c) *Reliable information which is currently available for determining benefits.* The Commissioner has determined that no reliable information exists which is currently available to use in determining benefit amounts.

(1) *Reliable information.* For purposes of this section "reliable information" means payment information that is maintained on a computer system of records by the government agency determining the payments (e.g., Department of Veterans Affairs, Office of Personnel Management for Federal civil service information and the Railroad Retirement Board).

(2) *Currently available information.* For purposes of this section "currently available information" means information that is available at such time that it permits us to compute and issue a correct benefit for the month the information is pertinent.

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[FR Doc. 97-14614 Filed 6-4-97; 8:45 am]

BILLING CODE 4190-29-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 184**

[Docket No. 86G-0289]

Substances Affirmed as Generally Recognized as Safe: Menhaden Oil

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that menhaden oil is generally recognized as safe (GRAS) as a direct human food ingredient with specific limitations. The agency is also affirming that partially

hydrogenated menhaden oil with an iodine number between 86 and 119 is GRAS as a direct human food ingredient with no limitation other than current good manufacturing practice. These actions complete the agency's response to a petition filed by the National Fish Meal and Oil Association.

DATES: Effective June 5, 1997. The Director of the Office of the Federal Register approves the incorporation by reference, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, of certain publications in 21 CFR 184.1472(a)(2), effective June 5, 1997.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFS-206), 200 C St. SW., Washington, DC 20204, 202-418-3103.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 170.35, the National Fish Meal and Oil Association, 2000 M St. NW., suite 580, Washington, DC 20036 (current address: 1525 Wilson Blvd., suite 500, Arlington, VA 22209), submitted a petition (GRASP 6G0316) seeking affirmation that menhaden oil and partially hydrogenated menhaden oil are GRAS for use as direct human food ingredients. The petition included information about the identity of, and manufacturing processes for, menhaden oil and partially hydrogenated menhaden oil; final reports and published articles of long-term animal feeding studies with partially hydrogenated menhaden oil; information about the history of human food use of partially hydrogenated menhaden oil; and the results of an extensive search of the published scientific literature (encompassing over 2,600 articles) with respect to the safety of fish oils in general.

FDA published a notice of filing of this petition in the **Federal Register** of July 31, 1986 (51 FR 27461), and gave interested persons an opportunity to submit comments to FDA's Dockets Management Branch. FDA received three comments, two from manufacturers and one from a government agency. All of the comments supported the affirmation of GRAS status for use of the oils in food.

FDA affirmed that partially hydrogenated menhaden oil (with an iodine number not more than 85) and fully hydrogenated menhaden oil are GRAS in the **Federal Register** of September 15, 1989 (54 FR 38219). These oils were affirmed as GRAS based on the chemical similarity between these oils and partially hydrogenated common edible vegetable oils, and on the established history of use in Europe