

[RIN # 2120-AG88 Revisions to Digital Flight Data Recorder Requirements for Airbus, Airplanes]

Parameters	Range	Accuracy (sensor input)	Seconds per sampling interval	Resolution	Remarks
15. Pitch Control Surface(s) Position. ⁶					
16. Lateral Control Surface(s) Position. ⁷					
17. Yaw Control Surface(s) Position. ⁸					
19. Pitch Trim Surface Position. ⁹					
20. Trailing Edge Flap or Cockpit Control Selection. ¹⁰					
23. Ground Spoiler Position or Speed Brake Selection. ¹²					
24. Outside Air Temperature or Total Air Temperature. ¹³					

¹ For A300 B2/B4 airplanes, resolution = 6 seconds.² For A330/A340 series airplanes, resolution = 0.703°.³ For A318/A319/A320/A321 series airplanes, resolution = 0.275% (0.088°>0.064°)

For A330/A340 series airplanes, resolution = 2.20% (0.703°>0.064°)

⁴ For A318/A319/A320/A321 series airplanes, resolution = 0.22% (0.088°>0.080°)

For A330/A340 series airplanes, resolution = 1.76% (0.703°>0.080°)

⁵ For A318/A319/A320/A321 series airplanes, resolution = 0.21% (0.088°>0.084°)

For A330/A340 series airplanes, resolution = 1.18% (0.703°>0.120°)

⁶ For A330/A340 series airplanes, resolution = 0.783% (0.352°>0.090°)⁷ For A330/A340/A320/A321 series airplanes, aileron resolution = 0.704% (0.352°>0.100°)

For A330/A340 series airplanes, spoiler resolution = 1.406% (0.703°>0.100°)

⁸ For A330/A340 series airplanes, resolution = 0.30% (0.176°>0.12°)

For A330/A340 series airplanes, seconds per sampling interval = 1

⁹ For all Airbus airplanes, resolution = 0.518% (0.088°>0.051°)¹⁰ For A330/A340 series airplanes, resolution = 1.05% (0.250°>0.120°)¹¹ For A330/A340 series airplanes, resolution = 1.05% (0.250°>0.120°)

For A300 B2/B4 series airplanes, resolution = 0.92% (0.230°>0.125°)

¹² For A300-600/A310 series airplanes, speed brake resolution = 0.224% (0.112°>0.100°)

For A330/A340 series airplanes, spoiler resolution = 1.406% (0.703°>0.100°)

¹³ For A330/A340 series airplanes, resolution = 0.5°C.

Issued in Washington, DC on August 17, 1999.

Jane F. Garvey,

Administrator.

[FR Doc. 99-21783 Filed 8-23-99; 8:45 am]

BILLING CODE 4910-13-M

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

RIN 0960-AE65

Revised Medical Criteria for Determination of Disability, Endocrine System and Related Criteria

AGENCY: Social Security Administration (SSA).

ACTION: Final rule.

SUMMARY: We are deleting listing 9.09, "Obesity," from appendix 1, subpart P of part 404, the "Listing of Impairments" (the listings). Although many individuals with obesity are appropriately found "disabled" within the meaning of the Social Security Act (the Act), we have determined that the criteria in listing 9.09 were not appropriate indicators of listing-level

severity because they did not represent a degree of functional limitation that would prevent an individual from engaging in any gainful activity. However, in response to public comments, we are adding guidance about evaluating claims for benefits involving obesity to the prefaces of the musculoskeletal, respiratory, and cardiovascular body system listings.

DATES: These regulations will be effective on October 25, 1999.

FOR FURTHER INFORMATION CONTACT:

Robert Augustine, Social Insurance Specialist, Office of Process and Innovation Management, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235-6401, (410) 966-5121 or TTY (410) 966-5609 for information about these rules. For information on eligibility or claiming benefits, call our national toll-free number, 1-800-772-1213 or TTY 1-800-325-0778.

SUPPLEMENTARY INFORMATION: Title II of the Act provides for the payment of disability insurance benefits to workers insured under the Act. Title II also provides, under certain circumstances, for the payment of child's insurance

benefits for persons who become disabled before age 22 and widow's and widower's insurance benefits based on disability for widows, widowers, and surviving divorced spouses of insured individuals. In addition, title XVI of the Act provides for supplemental security income (SSI) payments to persons who are aged, blind, or disabled and who have limited income and resources.

For adults under both the title II and title XVI programs and for persons claiming child's insurance benefits based on disability under the title II program, "disability" means that an impairment(s) results in an inability to engage in any substantial gainful activity. (For an individual under age 18 claiming SSI benefits based on disability, "disability" means that an impairment(s) results in "marked and severe functional limitations.") Under both title II and title XVI, disability must be the result of any medically determinable physical or mental impairment(s) that can be expected to result in death or that has lasted or can be expected to last for a continuous period of at least 12 months.

To determine whether an individual (except for an individual under age 18 claiming SSI benefits based on disability) is disabled based upon this statutory definition, our longstanding regulations at §§ 404.1520 and 416.920 provide for a five-step sequential evaluation process, as follows:

1. Is the individual engaging in substantial gainful activity? If the individual is working and the work is substantial gainful activity, we find that he or she is not disabled. Otherwise, we proceed to step 2 of the sequence.

2. Does the individual have an impairment or combination of impairments that is severe? If the individual does not have a severe impairment or combination of impairments, we find that he or she is not disabled. If the individual has a severe impairment or combination of impairments, we proceed to step 3 of the sequence.

3. Does the individual's impairment(s) meet or equal in severity the criteria of a listed impairment in appendix 1 of subpart P of part 404? Sections 404.1525(a) and 416.925(a) of our regulations explain that the listings describe, for each of the major body systems, impairments that are considered severe enough to prevent a person from doing any gainful activity. If an individual has an impairment(s) that meets or is equal in severity to the criteria of a listed impairment, we find that he or she is disabled. If not, we proceed to step 4 of the sequence.

4. Does the individual's impairment(s) prevent him or her from doing his or her past relevant work, considering his or her residual functional capacity? If not, we find that he or she is not disabled. If so, we proceed to step 5 of the sequence.

5. Does the individual's impairment(s) prevent him or her from performing other work that exists in significant numbers in the national economy, considering his or her residual functional capacity together with the "vocational factors" of age, education, and work experience? If so, we find that the individual is disabled. If not, we find that he or she is not disabled.

Section 416.924 of our regulations provides a separate sequential evaluation process for individuals under age 18 who claim eligibility for SSI based on disability. As in the sequential evaluation process for adults, we determine at step 3 of this process whether the child's impairment(s) meets or medically equals the requirements of any listing. At this step, we also consider whether the child's impairment(s) "functionally" equals the requirements of any listing that includes

disabling functional limitations among its criteria.

Although the listings are contained only in part 404, we incorporate them by reference in § 416.925 of subpart I of part 416. The listings are divided into part A and part B. We apply the criteria in part A in evaluating impairments of persons age 18 or over. We may also apply the criteria in part A in evaluating impairments in persons under age 18 if the disease processes have a similar effect on adults and children. Part B contains additional criteria that we only use to evaluate impairments of children under age 18 when the criteria in part A do not give appropriate consideration to the particular effects of the disease processes in childhood. In evaluating disability for a person under age 18, we first use the criteria in part B. If the criteria in part B do not apply, we will use the criteria in part A (see §§ 404.1525 and 416.925).

When we revised and published the listing on obesity and several other listings in the **Federal Register** on December 6, 1985 (50 FR 50068), we indicated that medical advances in disability evaluation and treatment, and program experience, would require that we periodically review and update the medical criteria in the listings. Accordingly, we published expiration dates ranging from 3 to 8 years for the listings in each of the body systems. These dates appeared in our regulations in the introductory statement before part A of the listings. We subsequently extended these dates in final rules published in the **Federal Register** on December 6, 1993 (58 FR 64121) and again on June 5, 1997 (62 FR 30746). Most recently, we published final rules on June 3, 1999 (64 FR 29786), extending the expiration date of these listings to July 2, 2001, for both part A, including the listings for the endocrine system and obesity (9.00), and part B. (There was no listing for obesity in part B.)

On March 11, 1998, we proposed to delete listing 9.09, "Obesity," and related provisions in the listings, and to rename the section "Endocrine System" (63 FR 11854). We are now adopting the proposed rules as final rules, with the changes discussed below. These changes will not affect the current expiration date for the endocrine system listings.

In these final rules, we are removing listing 9.09 because our experience adjudicating cases under this listing indicates that the criteria in the listing were not appropriate indicators of listing-level severity. In our experience, the criteria in listing 9.09 did not represent a degree of functional

limitation that would prevent an individual from engaging in any gainful activity. However, even though we have deleted listing 9.09, we are making some changes to the listings in response to public comments to ensure that obesity is still addressed in our listings.

A number of public commenters, including professional medical and advocacy organizations, submitted medical literature to us in support of their view that we should not delete listing 9.09. We carefully reviewed these comments and the medical literature cited to us. We also considered whether we should revise the obesity listing by clarifying the severity criteria related to the affected body systems in listing 9.09 (i.e., the musculoskeletal, respiratory and cardiovascular systems), or by making other changes in the listings suggested by the commenters. However, we concluded that, because of the widely varying effects obesity and related impairments may have on an individual's functioning, the only way we could be confident that individuals would be disabled under the listings would be to require the other impairments to meet or equal the severity of their respective listings. We also considered whether to raise the weights in the tables to the extent that the level of obesity would ensure that the individuals would be disabled based on weight alone. We chose not to revise the listing in this way because we would have had to raise the weights in the tables to such high levels that we would rarely use the listing.

In response to various concerns about the potential effects of removing all reference to obesity from the listings, we are adding guidance about the evaluation of claims for benefits involving obesity to the prefaces of the musculoskeletal, respiratory, and cardiovascular body system listings. Our purpose in making these changes is to ensure that adjudicators understand that we consider obesity to be a medically determinable impairment that can be the basis for a finding of disability, and that obesity in combination with other impairments must be considered when evaluating disability at the listings step and other steps of the sequential evaluation process. We are making this change to clarify our intent.

We also want to make clear that we are deleting listing 9.09 because we have determined that the listing is no longer an appropriate rule and because we were unable to propose a reliable alternative. However, we will continue to consider whether we can make improvements in our evaluation of claims filed by individuals with obesity. We intend to obtain information from

the medical community and other interested parties regarding our adjudication of claims of individuals with obesity. We also intend to provide guidance to our adjudicators about the evaluation of claims involving obesity in a Social Security Ruling. Social Security Rulings make available to the public our policy interpretations and provide uniform, binding guidance for all components of the SSA and the State agencies that make disability determinations for us.

The following is a detailed summary of the revisions, together with our reasons for the changes.

Regulatory Provisions

Revisions to Part A of Appendix 1

Table of Contents

We are deleting “and Obesity” from section 9.00 to reflect the deletion of listing 9.09.

1.00 Musculoskeletal System

3.00 Respiratory System

4.00 Cardiovascular System

We are adding new paragraphs 1.00F., 3.00I., and 4.00F. to the prefaces to the listings for the body systems named above. The paragraphs state clearly that we consider obesity to be a medically determinable impairment and remind adjudicators to consider its effects when evaluating disability. The provisions also remind adjudicators that the combined effects of obesity with other impairments can be greater than the effects of each of the impairments considered separately. They also instruct adjudicators to consider the effects of obesity not only under the listings but also when assessing a claim at other steps of the sequential evaluation process, including when assessing an individual's residual functional capacity.

9.00 Endocrine System

We are deleting “and Obesity” from the heading of this section of the listings to reflect the deletion of listing 9.09. We are also deleting the second and third paragraphs from the preface of 9.00 because they discussed aspects of the evaluation of obesity in connection with listing 9.09.

9.01 Category of Impairments, Endocrine System

We are deleting “and Obesity” from the heading of this listing to reflect the deletion of listing 9.09.

9.09 Obesity

We are deleting listing 9.09. In our experience, its criteria were not

appropriate indicators of listing-level severity because they did not represent a degree of functional limitation that would prevent an individual from engaging in any gainful activity. For example, listing 9.09A required a “[h]istory of pain and limitation of motion in any weight-bearing joint or the lumbosacral spine (on physical examination) associated with findings on medically acceptable imaging techniques of arthritis in the affected joint or lumbosacral spine.” While such findings certainly could be a cause of disability depending on their impact on a particular individual's functioning, the listing was not specific. It did not indicate any degree of pain, nor did it require current pain—only a history of pain—and did not indicate a degree of limitation of motion. Thus, the listing could have been satisfied with only minimal additional findings over and above the specified weight levels, even though many individuals with those findings in conjunction with the specified weight levels were not precluded from performing any gainful activity.

The same holds true for the other criteria in listing 9.09. Although the findings in listings 9.09B through 9.09E could be disabling in a given individual, in our experience the findings contained in these listings were not consistently so severe that they would warrant a presumption that an individual is incapable of performing any gainful activity. Indeed, only listings 9.09B and 9.09E specified laboratory values, but those findings might or might not have prevented an individual from performing any gainful activity.

Individuals with the kinds of additional impairments previously listed in 9.09 will still have their cases evaluated as appropriate under the listings for the affected body systems, and can still be found to have impairments that meet the requirements of those other listings. They may also be found to have impairments that equal the severity of other listings, considering the combined effect of obesity and the other impairments. Individuals whose impairments related to, or in combination with, obesity are not of listing-level severity will have their cases evaluated based on their residual functional capacity, and may be found disabled at step 5 of the sequential evaluation process.

Other Revisions

Introductory Text

We are deleting “and Obesity” from item 10 of the introductory text that precedes part A of the listings. We are

also revising item 10 of the introductory text to read “Endocrine System (9.00 and 109.00): July 7, 1999.”

3.00 Respiratory System

We are deleting the last sentence of 3.00H, which referred to the obesity listing. We are also deleting the reference to listing 9.09 in listing 3.10, *Sleep-related breathing disorders*.

Public Comments

When we published the Notice of Proposed Rulemaking (NPRM) on March 11, 1998 (63 FR 11854), we provided the public with a 60-day comment period. On June 10, 1998, we extended the comment period until July 13, 1998 (63 FR 31680).

We received comments from just over 500 individuals and organizations. Almost 300 of the comment letters were form letters that included comments on subjects unrelated to the deletion of listing 9.09; we have forwarded the comments on the unrelated issues to the appropriate components within SSA and do not address them below. The other comment letters included detailed comments submitted on behalf of advocacy organizations representing individuals with obesity, medical researchers and medical advocates for individuals with disability, and legal advocates for individuals with obesity. We also received comments from some State agencies that make disability determinations for us, organizations representing disability adjudicators at the State level, several legal services organizations, individual disability beneficiaries and their families, attorneys, non-attorney representatives, and SSA employees.

When we proposed these rules, we stated that we intended to delete the obesity listing because “[c]urrent medical and vocational research demonstrates that, while many individuals with obesity are disabled, obesity, in and of itself, is not necessarily determinative of an individual's inability to engage in any gainful activity” (63 FR 11854). A number of the comments (discussed more fully below) indicated that there may have been some misunderstanding about why we were proposing to remove the listing. Therefore, in addition to responding to the specific comments, we want to provide a fuller explanation of why we are making the change.

Some commenters believed that we claimed that we had conducted extensive research, that this research was the sole basis for our proposal, but that we were not making this research available to the public. This was not the

case, and it was not what we meant in the NPRM.

We proposed to delete listing 9.09 primarily because our program and adjudicative experience helped to convince us that the listing was difficult to administer, subject to misinterpretation, and required findings of disability in some cases in which the claimants were clearly not "disabled" as defined in the Act. Some of the criteria, such as the criteria in listings 9.09A and D, were vague and overly subjective. Some, such as the criteria in listings 9.09A and C, did not necessarily relate to current impairment status. These concerns were echoed by some of the comments from our adjudicators, who also noted that the listing was problematic.

Over the years, we had received many questions from adjudicators and others about the meaning of the criteria and how to apply them. We also had extensive experience reviewing individual claims that adjudicators referred to us for advice and for resolution of questions about the correct interpretation of the criteria. This experience convinced us that listing 9.09 was no longer appropriate.

In addition, before we published the NPRM, we reviewed a small group of cases in which individuals were found disabled based on a finding that their impairments met or equaled listing 9.09. Although our reviews did not constitute a statistically valid study, they did provide further confirmation of our program and adjudicative experience. We found that, in the majority of the cases we studied, the determinations would not have been affected by the deletion of listing 9.09; i.e., we would have found the individuals disabled. The majority of individuals had impairments that met or equaled other listings, or that we would have found disabling at step 5 of the sequential evaluation process; most of these individuals had impairments that met or equaled other listings. However, consistent with our experience, we also found that, in a significant number of the cases, we would not have found the individuals disabled under other listings or at step 5 of the sequential evaluation process.

We also reviewed medical literature to see if any generally accepted research showed a correlation between obesity and loss of functional capacity for work that might support retention of the listing without change or serve as a basis for an alternative proposal. There is significant medical literature correlating obesity with a variety of health risks. A number of commenters cited such literature to us; one comment

letter cited many such sources. However, we reviewed the cited sources and determined that they did not provide support for the retention of listing 9.09 because they did not demonstrate a significant correlation between obesity and current loss of functional ability for work. Although the sources did show that the risk for having another impairment goes up significantly if an individual is severely obese, they did not provide a basis for concluding that a given individual will currently be unable to engage in any gainful activity.

For all the foregoing reasons, we have decided that we must delete listing 9.09 and that it is most appropriate to evaluate disability under the listings for the other impairments an individual with severe obesity might have. We also concluded that we should instruct our adjudicators that the combined effects of obesity with other impairments may be greater than the effects of each of the impairments considered separately, and that such evaluations should be made on an individualized, case-by-case basis.

Summaries of the significant comments and our responses follow. Because some of the comments were quite detailed, we had to condense, summarize, or paraphrase them. We have, however, tried to summarize the commenters' views accurately and have responded to all of the significant issues raised by the commenters that are within the scope of the proposed rules. As we discuss below in responding to the comments, we have made revisions and additions in the final rules to clarify our intent.

Comment: A number of commenters said that deleting listing 9.09 will result in longer, more costly, and less consistent determinations and decisions, and will also result in increased case backlogs. They said that the listing saved administrative resources by using objective medical criteria to avoid a more costly case-by-case inquiry into an individual's functional ability.

Response: Although some individual cases will require more development and analysis than they would have under listing 9.09, in our cost/benefit analysis, we estimate that, overall, there will be slight administrative savings from these final rules when all future actions are considered. For example, even though some cases will require more initial development than under listing 9.09, there will be fewer continuing disability reviews because we anticipate there will be fewer people whose claims will be allowed than under the prior rules. Moreover, obesity is the primary impairment in just under

3 percent of all disability claims filed each year under titles II and XVI. Also, as we have already noted, there will be no effect on many cases because many of the individuals with severe obesity who file applications each year and who would have met listing 9.09 will be found to have impairments that meet or equal other listings based on the medical and other evidence we obtain in our routine development of all cases.

With regard to the second part of the comment, and as we have noted earlier in this preamble, we do not agree that listing 9.09 was objective or accurate as a measure of listing-level impairment severity in a significant number of cases.

Comment: Many commenters thought that deletion of listing 9.09 would result in the denial of benefits to disabled individuals. Many of the commenters believed that without listing 9.09, adjudicators would overlook or improperly evaluate a claimant's obesity. Some stated that obesity is a disease that can affect an individual's ability to stand, sit, walk, climb, etc., and should be treated as such. They said that for SSA to eliminate this impairment from the listings would be to ignore a genuine medical impairment that causes significant functional limitations.

Some commenters thought that removing any reference to obesity from our listings would send an implicit message to our adjudicators that we do not want them to consider obesity. Several commenters expressed concern that adjudicator "bias" would play a part in case evaluation in the absence of the obesity listing.

Many commenters also indicated that listing 9.09 did not consider obesity alone. They thought that adjudicators would not adequately consider obesity, either under the listings for other body systems, which do not provide criteria that specifically take into account the effects of obesity, or in the assessment of an individual's residual functional capacity.

Most of these commenters urged us to retain some reference to obesity and its potentially disabling manifestations in our rules.

Response: We made revisions in these final rules in response to the comments. Our proposal to delete listing 9.09 neither stated nor implied that we would no longer consider obesity to be a medically determinable impairment, nor did it state or imply that obesity could not be disabling by itself or in combination with other impairments. We agree, however, that our rules should retain some reference to obesity and its potentially disabling manifestations.

Obesity is a medically determinable impairment, and we expect our adjudicators to consider it when evaluating impairment severity. Adjudicators must also incorporate any functional limitations resulting from obesity into the assessment of disability. We are confident that our adjudicators will continue to do so, even in the absence of listing 9.09. We also have a quality assurance review process that helps us ensure that decisions are supported by the evidence and that multiple impairments, including obesity, are properly considered.

Nevertheless, we agree with the commenters that there could have been a potential for misinterpretation of our intent if we simply deleted references to obesity in the listings without anything more. Therefore, in response to the comments, we have added paragraphs to the prefaces of the musculoskeletal, respiratory, and cardiovascular body systems (the same body systems that were referenced in listings 9.09 A through E), to indicate that we consider obesity to be a medically determinable impairment, that obesity is often associated with disturbances of these body systems, and that disturbances of these body systems can be a major cause of disability in individuals with obesity. We also provide that the combined effects of obesity with impairments in these body systems can be greater than the effects of each of the impairments considered separately. Finally, we provide that, when determining whether an individual with obesity has a listing-level impairment or combination of impairments, and when assessing residual functional capacity, adjudicators must consider any additional and cumulative effects of obesity. In addition, as noted above, we intend to provide additional guidance to our adjudicators about the evaluation of claims involving obesity in a Social Security Ruling.

Comment: Many commenters stated that listing 9.09 was a carefully drafted regulation that recognized the impact of obesity on certain musculoskeletal, respiratory, and cardiovascular disorders. They said the listing correctly reflected that severe obesity, in conjunction with any of the conditions set forth in listings 9.09 A through E, would result in functional limitations so severe that the individual would not be able to meet the performance or attendance requirements of any employer. They asked that we keep the listing without change.

Response: The listing criteria for obesity we first promulgated on March 27, 1979 (44 FR 18170), represented our attempt to devise criteria that would

“take into account the contributing complication of obesity . . .” (44 FR 18175). However, for the reasons previously discussed, we believe that the listing did not easily or accurately distinguish between individuals who could be presumed to be unable to engage in any gainful activity and those for whom such a presumption was inappropriate.

Comment: Many commenters urged us to revise, rather than delete, the obesity listing, and some offered to assist us in developing new listing criteria. Some recommended specific revisions to the current listing, such as revising the requirements in sections A through E of the listing or converting the listing to a “reference” listing; that is, one that merely cross-refers to other listings. Others suggested that we incorporate specific criteria for obesity in appropriate listings in other body systems (e.g., musculoskeletal, respiratory, cardiovascular, mental) so that adjudicators would not overlook it in determining the severity of an individual’s impairments.

Response: We added paragraphs to the prefaces to other body system listings that we believe address the concerns of many of the commenters who encouraged us, in one way or another, to retain reference to obesity in the listings. However, we did not adopt the commenters’ suggestions for alternative criteria based either on a specific level of obesity alone or on a level of obesity in conjunction with another impairment that is itself of less than listing-level severity. None of the alternative criteria proposed by commenters appeared to describe a level of impairment severity that would allow us reasonably to conclude that an individual who met the alternative criteria would be unable to perform any gainful activity.

Comment: Several commenters were concerned that the proposal to eliminate listing 9.09 was based on assumptions concerning functional capacity. They said that functional capacity has never been a consideration in determining whether an adult claimant meets the listings.

Response: Functioning is an explicit criterion in many of our listings. Moreover, even though we do not assess functional limitations in some listings, §§ 404.1525 and 416.925 of our regulations provide that the listings describe impairments that are considered severe enough to prevent a person from doing any gainful activity.

Comment: A few commenters objected to our statement that some individuals who met listing 9.09 might be able to perform substantial gainful

activity. They did not believe that the listing differed from any of the other listings in that regard, pointing out that individuals with impairments that would meet listings often work. They contended that individuals with the level of obesity and the additional impairment required by the listing were as disabled as anyone who met or equaled any other listing.

Response: Our listings are intended to readily identify individuals who would ultimately be found disabled if they were not already working, and if we considered their residual functional capacity, age, education, and work experience. We know that there are individuals who work despite impairments of the severity reflected in our listings, but we believe that in general the listings are a useful tool for identifying many people who should qualify under our rules. However, based on our program and adjudicative experience, we do not agree with the commenters that listing 9.09 was as accurate an indicator of disability as other listings.

Comment: Some commenters indicated confusion about our statement in the NPRM that obesity in and of itself is not necessarily determinative of an individual’s inability to engage in any gainful activity, and other, similar statements. The commenters pointed out that listing 9.09 did not consider obesity in and of itself; rather, it provided criteria for obesity associated with other impairments.

Response: We agree that listing 9.09 did not consider obesity alone. We intended this statement only to help explain why we did not propose other alternatives to deleting listing 9.09, including a listing for obesity alone.

Comment: Several commenters questioned whether we were targeting impairments with a “volitional” aspect for removal from the listings, citing the removal of drug addiction and alcoholism as a basis for disability.

Response: We are not targeting specific kinds of impairments for review or exclusion from the listings, nor do we believe that obesity and other medical impairments are “volitional.” In December 1985, when we last published final rules containing comprehensive revisions to the listings, we stated that medical advancements in disability evaluation and treatment and program experience would require that the listings be periodically reviewed and updated. These final rules are consistent with our longstanding responsibility to monitor the effectiveness of the listings, so that we can ensure they remain an appropriate and efficient tool to evaluate claims for disability.

The changes to our rules on the evaluation of drug addiction and alcoholism were required by law.

Comment: We received a number of comments on the many causes of obesity and the general ineffectiveness of current treatments. Many commenters cited the increased risk for developing musculoskeletal, respiratory, and cardiovascular problems, and for premature death. They pointed out that when we published revised listings in 1985, we explained that medical advances in treatment and program experience would require periodic evaluation and revision of the listings. They asked what advances in medicine or program experience justified eliminating the obesity listing.

Response: We do not dispute the commenters' statements about the causes of obesity and the general ineffectiveness of current treatments. As noted previously, the changes we are making are not the result of advances in medical evaluation or treatment but the result of program and adjudicative experience.

We also do not dispute the comments that individuals with severe obesity have increased morbidity and mortality risks. However, under the Act and our regulations we must consider whether an individual is currently disabled. We do not consider whether an individual is at risk for disability sometime in the future. The changes we are making in these final rules will enable us to assess disability based on the actual effects (as opposed to potential future effects) of the impairment.

Comment: Some commenters were concerned that many individuals would lose their benefits and have no means of assistance if we were to delete listing 9.09. One commenter recommended that we review all prior allowances based on listing 9.09 under the new rules.

Response: No individual will be removed from the rolls solely because we have deleted listing 9.09, as some commenters suggested. We will not review prior allowances based on listing 9.09 under the new rules.

These final rules have only a prospective effect. Unless otherwise required to do so (for example, by statute), we do not readjudicate previously decided cases when we revise our listings.

We do conduct periodic "continuing disability reviews" of individuals on our rolls to determine whether they are still disabled. However, when we conduct continuing disability reviews, we do not find that disability has ended based on a change in a listing. In most cases, we must show that an

individual's impairment(s) has medically improved and that any medical improvement is "related to the ability to work." If an individual's impairment(s) has not medically improved, we will generally find that the individual is still disabled. Even if the impairment(s) has medically improved, our regulations provide that the improvement is not "related to the ability to work," if the impairment(s) continues to meet or equal the "same listing section used to make our most recent favorable decision." This is true even if, as in these final rules, we have deleted the listing section that we used to make the most recent favorable decision. See §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A) of our regulations. (A similar provision for continuing disability reviews for children eligible for SSI based on disability appears in § 416.994a(b)(2)). In a case where we find that medical improvement is not related to the ability to work (or the impairment still meets or equals the prior listing, in the case of an individual under age 18), we will find that disability continues, unless an exception to medical improvement applies.

Comment: Some commenters supported our proposal, but had questions about how claims for benefits involving obesity would be adjudicated after the deletion.

Response: We believe that the new paragraphs we have added to the prefaces of the musculoskeletal, respiratory, and cardiovascular body system listings in the final rules provide guidance for our adjudicators in the proper handling of claims involving obesity. In addition, as we have noted above, we intend to provide additional guidance to our adjudicators regarding the evaluation of claims involving obesity, by issuing a Social Security Ruling.

Comment: Several commenters stated that the proposed change would have a disproportionate impact on particular groups of individuals, such as women, minorities and individuals at lower socioeconomic levels. They thought the proposed rule discriminatory. Some commenters thought the rules reflected societal prejudice against individuals with obesity. Some said, without explanation, that deleting the obesity listing would violate the Americans with Disabilities Act (ADA), 42 U.S.C. 12101 *et seq.*, or the Rehabilitation Act of 1973, 29 U.S.C. 794.

Response: SSA is committed to providing fair treatment for all individuals who seek or receive benefits. The deletion of listing 9.09 means only that individuals with severe

impairments who seek benefits based in whole or in part on obesity will have their claims evaluated in accordance with the appropriate body system in the listings, or at later steps of the sequential evaluation process, as we explained in the proposed rules (63 FR 11854, 11855) and above. Our actions in these final rules in no way violate the ADA or the Rehabilitation Act; they are intended to help us ensure that only those individuals who meet the statutory definition of disability are found disabled.

These final rules do not discriminate against any individual or group of individuals based on their impairments. Rather, they ensure that our listings remain an efficient and legally appropriate method for determining that individuals who meet the statutory definition of disability are found disabled, and that individuals who do not meet the statutory definition are not inappropriately found disabled. In our experience, listing 9.09 did not always meet that goal. Consequently, we believe that the best course of action is to delete the listing.

This does not mean that these final rules reflect prejudice against individuals with obesity, or that they are intended to result in discriminatory treatment of any individuals. However, to ensure that adjudicators understand our intent, we have added guidance to the musculoskeletal, respiratory, and cardiovascular body system listings as described above. We believe the changes we have made to the listings will ensure that disability claims based on obesity are evaluated appropriately.

Comment: One commenter said that the proposed rule violated the Administrative Procedure Act (APA) because the agency did not disclose any scientific and technical studies or data in the NPRM. This commenter asserted that the APA requires the agency to disclose scientific material that the agency believes supports its rule to interested parties for comment. Another commenter expressed similar views and asserted that the NPRM violated the APA because the commenter believed it relied on inadequate data.

Response: In the Supplementary Information section of the preamble to the NPRM, we noted that "[c]urrent medical and vocational research demonstrates that the listing is not necessarily reflective of an inability to engage in any gainful activity or even of an inability to engage in substantial gainful activity" (63 FR 11854, 11855). We made a similar comment in the Summary section of the preamble of the NPRM (63 FR 11854). We also noted that we were proposing to remove

listing 9.09 "to recognize that there is no generally accepted current medical and vocational knowledge which establishes that even massive obesity, per se, has a defined adverse effect on an individual's ability to work; i.e., even long-term, massive obesity at the level specified in the listing does not necessarily cause limitations that would prevent an individual from engaging in any gainful activity" (63 FR 11855).

We regret that these statements may have caused some confusion. As we discussed earlier in this preamble, we did not mean to imply that we were relying on any specific research to justify our decision to propose the removal of listing 9.09. Rather, we intended these statements to mean only that there is no generally accepted current medical and vocational knowledge which establishes that even massive obesity, per se, has a defined adverse effect on an individual's ability to work.

In response to these statements in the preamble to the proposed rule, a number of commenters provided us with citations to medical research and other medical literature (e.g., medical manuals and textbooks). The commenters believed the research they cited supported their position that obesity has a specific adverse impact on an individual's functional abilities, such that it results in disability. We have reviewed the medical research and other documents that have been brought to our attention by the commenters, and believe that they are consistent with our experience in adjudicating cases under listing 9.09 or otherwise did not provide a basis for retaining the listing. None of the sources that have been brought to our attention by the commenters, or that we reviewed in the course of developing these final rules, support the conclusion that obesity at the level specified in listing 9.09, taken in conjunction with the findings related to any associated musculoskeletal, respiratory, or cardiovascular impairments set out in listings 9.09A through E, would necessarily have such an adverse impact on an individual's functional abilities that it should be considered to preclude the performance of any gainful activity, in the absence of a case-by-case determination of the effects of the obesity and associated impairments on a particular individual.

We believe our actions in proposing the deletion of listing 9.09 are fully consistent with the APA and have provided the public with a meaningful opportunity to comment on the proposed rule. In fact, we extended the comment period to provide additional time for comment. Moreover, the

supplemental data contained in the studies that were brought to our attention by various commenters did not provide a basis for changing the proposal. We do not believe, therefore, that the APA requires us to withdraw the proposed rule and initiate additional rulemaking, as some commenters suggested.

Comment: Some commenters said that SSA used an unfair and cursory approach in proposing to delete the obesity listing and that we could use the same approach and rationale to delete any listing. They said that SSA's professional image and reputation for commitment to individual equity and due process would be threatened if we proceeded with the proposed deletion.

Response: We have long recognized that medical advances in disability evaluation and treatment and program experience require that we periodically review and update the medical criteria in the listings. On an ongoing basis, we review medical literature and our program and adjudicative experience to monitor the medical criteria in the listings. We do not recommend changes without careful consideration. We do not believe our approach in this case was unfair or cursory.

Accordingly, for the reasons set out above, we are publishing the proposed rules as final rules with the revisions noted.

Regulatory Procedures

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these final regulations meet the criteria for a significant regulatory action under Executive Order (E.O.) 12866. Therefore, we prepared and submitted to OMB an assessment of the potential costs and benefits of this regulatory action. This assessment also contains an analysis of alternative policies we considered and chose not to adopt. It is available for review by members of the public by contacting the person shown above.

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

Paperwork Reduction Act

These final regulations will impose no new reporting or recordkeeping requirements requiring OMB clearance.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability 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: April 7, 1999.

Kenneth S. Apfel,

Commissioner of Social Security.

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

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

1. The authority citation for subpart P 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.

Appendix 1 to Subpart P of Part 404—Listing of Impairments

2. Item 10 of the introductory text before Part A of appendix 1 is revised to read as follows:

* * * * *

10. Endocrine System (9.00 and 109.00):
July 2, 2001.

* * * * *

3. The Table of Contents for Part A of appendix 1 is amended by removing "and Obesity" from section 9.00.

4. Listing 1.00 in part A of appendix 1 is amended by adding new paragraph F. to read as follows:

1.00 Musculoskeletal System

* * * * *

F. *Effects of obesity.* Obesity is a medically determinable impairment that is often associated with disturbance of the musculoskeletal system, and disturbance of this system can be a major cause of disability in individuals with obesity. The combined effects of obesity with musculoskeletal impairments can be greater than the effects of each of the impairments considered separately. Therefore, when determining whether an individual with obesity has a listing-level impairment or combination of impairments, and when assessing a claim at other steps of the sequential evaluation process, including when assessing an individual's residual functional capacity, adjudicators must

consider any additional and cumulative effects of obesity.

5. Listing 3.00 in part A of appendix 1 is amended by removing the last sentence of paragraph H and adding new paragraph I. to read as follows:

3.00 Respiratory System

* * * * *

I. *Effects of obesity.* Obesity is a medically determinable impairment that is often associated with disturbance of the respiratory system, and disturbance of this system can be a major cause of disability in individuals with obesity. The combined effects of obesity with respiratory impairments can be greater than the effects of each of the impairments considered separately. Therefore, when determining whether an individual with obesity has a listing-level impairment or combination of impairments, and when assessing a claim at other steps of the sequential evaluation process, including when assessing an individual's residual functional capacity, adjudicators must consider any additional and cumulative effects of obesity.

6. Listing 3.10 in Part A of appendix 1 is revised to read as follows:

3.10 *Sleep-related breathing disorders.* Evaluate under 3.09 (chronic cor pulmonale) or 12.02 (organic mental disorders).

7. Listing 4.00 in Part A of appendix 1 is amended by adding new paragraph F. to read as follows:

4.00 Cardiovascular System

* * * * *

F. *Effects of obesity.* Obesity is a medically determinable impairment that is often associated with disturbance of the cardiovascular system, and disturbance of this system can be a major cause of disability in individuals with obesity. The combined effects of obesity with cardiovascular impairments can be greater than the effects of each of the impairments considered separately. Therefore, when determining whether an individual with obesity has a listing-level impairment or combination of impairments, and when assessing a claim at other steps of the sequential evaluation process, including when assessing an individual's residual functional capacity, adjudicators must consider any additional and cumulative effects of obesity.

8. Listing 9.00 in part A of appendix 1 is amended by removing "AND OBESITY" from the title and removing the last two paragraphs from the preface.

9. Listing 9.01 in part A of appendix 1 is amended by removing "and Obesity" from the title.

10. Listing 9.09 in part A of appendix 1 is removed.

[FR Doc. 99-21935 Filed 8-23-99; 8:45 am]

BILLING CODE 4190-29-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 96F-0145]

Indirect Food Additives: Paper and Paperboard Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of tetrakis(hydroxymethyl)phosphonium sulfate (CAS Reg. No. 55566-30-8) as a slimicide for use in the manufacture of paper and paperboard that contact food. This action responds to a petition filed by Albright & Wilson, Ltd.

DATES: This regulation is effective August 24, 1999; submit written objections and requests for a hearing by September 23, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vivian M. Gilliam, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3094.

SUPPLEMENTARY INFORMATION:

In a notice published in the **Federal Register** of May 20, 1996 (61 FR 25228), FDA announced that a food additive petition (FAP 5B4472) had been filed by Albright & Wilson, Ltd., c/o Delta Analytical Corp., 7910 Woodmont Ave., suite 1000, Bethesda, MD 20814. The petition proposed to amend the food additive regulations in § 176.300 *Slimicides* (21 CFR 176.300) to provide for the safe use of tetrakis(hydroxymethyl)phosphonium sulfate as a slimicide in the manufacture of paper and paperboard intended to contact food. Albright and Wilson, Ltd. is currently represented by Lewis & Harrison, 122 C St. NW., suite 740, Washington, DC 20001. (Formerly represented by Delta Analytical Corp., 7910 Woodmont Ave., suite 1000, Bethesda, MD 20814.)

When the petition was filed on May 20, 1996, it contained an environmental assessment (EA). In the notice of filing, the agency announced that it was placing the EA on display at the Dockets Management Branch for public review

and comment (61 FR 25228). No comments were received. On July 29, 1997 (62 FR 40569), FDA published revised regulations under part 25 (21 CFR part 25), which became effective on August 28, 1997. On January 7, 1999, the petitioner submitted a claim of categorical exclusion under new § 25.32(q), in accordance with the procedures in § 25.15(a) and (d). Because the agency had not completed its review of the earlier submitted EA, the agency reviewed the claim of categorical exclusion under § 25.32(q) for the final rule and has determined that this action is a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an EA nor an environmental impact statement is required.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of tetrakis(hydroxymethyl)phosphonium sulfate as a slimicide in the manufacture of paper and paperboard that contact food is safe; (2) the additive will achieve its intended technical effect; and therefore, (3) the regulation in § 176.300(c) should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before September 23, 1999, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for