

Frederick, MD, Frederick Muni, RNAV (GPS) RWY 23, Amdt 2

Gaithersburg, MD, Montgomery County Airpark, RNAV (GPS) RWY 14, Amdt 1

Gaithersburg, MD, Montgomery County Airpark, RNAV (GPS) RWY 32, Orig

New York, NY, La Guardia, VOR/DME-E, Amdt 2A

New York, NY, La Guardia, VOR-F, Amdt 2A

New York, NY, La Guardia, VOR/DME-G, Amdt 2A

New York, NY, La Guardia, RNAV (GPS) RWY 22, Orig

New York, NY, La Guardia, RNAV (GPS) RWY 31, Orig

New York, NY, La Guardia, RNAV (GPS) RWY 4, Orig

New York, NY, La Guardia, ILS RWY 22, Amdt 19

New York, NY, La Guardia, VOR/DME-H, Amdt 2A

New York, NY, La Guardia, NDB RWY 22, Amdt 12C

New York, NY, La Guardia, NDB RWY 4, Amdt 36A

Midland, TX, Midland Intl, RNAV (GPS) RWY 4, Orig

Midland, TX, Midland Intl, RNAV (GPS) RWY 16R, Orig

Midland, TX, Midland Intl, RNAV (GPS) RWY 22, Orig

Midland, TX, Midland Intl, RNAV (GPS) RWY 28, Orig

Midland, TX, Midland Intl, RNAV (GPS) RWY 34L, Orig

Midland, TX, Midland Intl, GPS RWY 16R, Orig, CANCELLED

Midland, TX, Midland Intl, GPS RWY 34L, Orig, CANCELLED

Midland, TX, Midland Intl, VOR/DME RNAV RWY 16R, Amdt 3A, CANCELLED

Midland, TX, Midland Intl, VOR/DME RNAV RWY 34L, Amdt 2, CANCELLED

Leesburg, VA, Leesburg Executive, RNAV (GPS) RWY 17, Orig

Leesburg, VA, Leesburg Executive, GPS RWY 17, Amdt 1A, CANCELLED

Manassas, VA, Manassas Regional/Harry P. Davis Field, GPS RWY 16L, Orig-A, CANCELLED

Manassas, VA, Manassas Regional/Harry P. Davis Field, RNAV (GPS) RWY 16L, Orig

* * * *Effective October 2, 2003*

Savannah, GA, Savannah/Hilton Head Intl, RNAV (GPS) RWY 9, Orig-A

Savannah, GA, Savannah/Hilton Head Intl, RNAV (GPS) RWY 18, Orig-A

Savannah, GA, Savannah/Hilton Head Intl, RNAV (GPS) RWY 27, Orig-A

Savannah, GA, Savannah/Hilton Head Intl, RNAV (GPS) RWY 36, Orig-A

* * * *Effective October 30, 2003*

Atlanta, GA, Cobb County-McCollum Field, RNAV (GPS) RWY 9, Orig-A

Atlanta, GA, Cobb County-McCollum Field, RNAV (GPS) RWY 27, Orig-A

Atlanta, GA, Cobb County-McCollum Field, VOR/DME RWY 9, Orig-F

Atlanta, GA, Cobb County-McCollum Field, ILS RWY 27, Amdt 1A

Blackfoot, ID, McCarley Field, VOR/DME RWY 19, Orig, CANCELLED

Portland, ME, Portland Intl Jetport, NDB RWY 11, Amdt 15B

Portland, ME, Portland Intl Jetport, ILS OR LOC RWY 11, Orig

Portland, ME, Portland Intl Jetport, ILS OR LOC RWY 29, Orig

Portland, ME, Portland Intl Jetport, RNAV (GPS) RWY 11, Orig

Portland, ME, Portland Intl Jetport, RNAV (GPS) RWY 29, Orig

Portland, ME, Portland Intl Jetport, ILS RWY 11, Amdt 20, CANCELLED

Portland, ME, Portland Intl Jetport, ILS RWY 29, Orig, CANCELLED

Duncan, OK, Halliburton Field, VOR RWY 35, Amdt 11

Duncan, OK, Halliburton Field, RNAV (GPS) RWY 17, Orig

Duncan, OK, Halliburton Field, RNAV (GPS) RWY 35, Orig

Duncan, OK, Halliburton Field, GPS RWY 35, Orig-A, CANCELLED

Milwaukee, WI, General Mitchell Intl, ILS RWY 1L, Amdt 8

Milwaukee, WI, General Mitchell Intl, ILS RWY 7R, Amdt 15

Milwaukee, WI, General Mitchell Intl, ILS RWY 19R, Amdt 10

Milwaukee, WI, General Mitchell Intl, NDB RWY 1L, Amdt 4B

Milwaukee, WI, General Mitchell Intl, NDB RWY 7R, Amdt 10D

Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 1L, Orig

Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 1R, Orig

Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 7R, Orig

Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 7L, Orig

Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 13, Orig

Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 19L, Orig

Milwaukee, WI, General Mitchell Intl, RNAV (GPS) Y RWY 19R, Orig

Milwaukee, WI, General Mitchell Intl, RNAV (GPS) Z RWY 19R, Orig

Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 25L, Orig

Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 25R, Orig

Milwaukee, WI, General Mitchell Intl, RNAV (GPS) RWY 31, Orig

[FR Doc. 03-21766 Filed 8-27-03; 8:45 am]

BILLING CODE 4910-13-P

SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Regulations No. 4 and 16]

RIN 0960-AF95

Revised Medical Criteria for Evaluating Amyotrophic Lateral Sclerosis

AGENCY: Social Security Administration
ACTION: Final rules.

SUMMARY: We are revising the criteria in the Listing of Impairments (the listings) that we use to evaluate Amyotrophic Lateral Sclerosis (ALS). We apply these criteria when you claim benefits based

on disability under title II or title XVI of the Social Security Act (the Act). The revision provides that we will find you disabled if you have medical evidence showing that you have ALS.

Because of this change, we are also adding guidance about ALS to our listings. We are also adding ALS to the list of specific impairment categories in our regulation that provides for presumptive disability payments under title XVI.

DATES: These rules are effective August 28, 2003.

FOR FURTHER INFORMATION CONTACT: Martin Sussman, Regulations Officer, Social Security Administration, 100 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235-6401, (410) 965-1767 or TTY (410) 966-5609. For information on 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, *Social Security Online*, at <http://www.socialsecurity.gov>.

Electronic Version: The electronic file of this document is available on the date of publication in the **Federal Register** at <http://www.gpoaccess.gov/fr/index.html>. It is also available on the Internet site for SSA (*i.e.*, Social Security Online): <http://www.socialsecurity.gov/regulations>.

SUPPLEMENTARY INFORMATION: For the reasons we explain below, we are revising listing 11.10, our listing for ALS, in our neurological body system listings. The new listing provides that we will find you disabled if you have medical evidence that shows that you have ALS. Because of this change, we are also making two additional changes:

- We are adding a new section 11.00G to the introductory material to the neurological listings to provide information about ALS and the evidence we need so that we can evaluate ALS under the new listing.

- We are amending § 416.934 of our regulations to include ALS on the list of "specific impairment categories" our field offices and State agencies use to make findings of presumptive disability under the Supplemental Security Income (SSI) program. This change will allow us to make findings of presumptive disability in claims involving allegations of ALS, without obtaining any medical evidence. We are also making a nonsubstantive technical change to the specific impairment category for Down syndrome in § 416.934, so that the category reflects the current terminology for the condition.

What Programs Do These Final Regulations Affect?

These final regulations affect disability determinations and decisions that we make under title II and title XVI of the Act. In addition, to the extent that Medicare entitlement and Medicaid eligibility are based on whether you qualify for disability benefits under title II or title XVI, these final regulations also affect the Medicare and Medicaid programs.

Who Can Get Disability Benefits?

Under title II of the Act, we provide for the payment of disability benefits if you are disabled and belong to one of the following three groups:

- Workers insured under the Act,
- Children of insured workers, and
- Widows, widowers, and surviving divorced spouses (see § 404.336) of insured workers.

Under title XVI of the Act, we provide for SSI payments on the basis of disability if you are disabled and have limited income and resources.

How Do We Define Disability?

Under both the title II and title XVI programs, the Act says that disability must be the result of any medically determinable physical or mental impairment or combination of impairments that is expected to result in death or which has lasted or is expected to last for a continuous period of at least 12 months. Our definitions of disability are shown in the following table:

If you file a claim under . . .	And you are . . .	Disability means you have a medically determinable impairment(s) as described above and that results in . . .
title II	an adult or child	the inability to do any substantial gainful activity (SGA).
title XVI	an individual age 18 or older	the inability to do any SGA.
title XVI	an individual under age 18	marked and severe functional limitations.

How Do We Decide Whether You Are Disabled?

To decide whether you are disabled under the Act, we use a five-step “sequential evaluation process,” which we describe in our regulations at §§ 404.1520 and 416.920. We follow the five steps in order and stop as soon as we can make a determination or decision. The steps are:

1. Are you working, and is the work you are doing substantial gainful activity? If you are working and the work you are doing is substantial gainful activity, we will find that you are not disabled, regardless of your medical condition or your age, education, and work experience. If you are not, we will go on to step 2.
2. Do you have a “severe” impairment? If you do not have an impairment or combination of impairments that significantly limits your physical or mental ability to do basic work activities, we will find that you are not disabled. If you do, we will go on to step 3.
3. Do you have an impairment(s) that meets or equals the severity of an impairment in the listings? If you do, and the impairment(s) meets the duration requirement, we will find that you are disabled. If you do not, we will go on to step 4.
4. Does your impairment(s) prevent you from doing your past relevant work? If it does not, we will find that you are not disabled. If it does, we will go on to step 5.
5. Does your impairment(s) prevent you from doing any other work, considering your residual functional capacity, age, education, and work experience? If it does, and it meets the duration requirement, we will find that

you are disabled. If it does not, we will find that you are not disabled.

We use different sequential evaluation processes for children who apply for disability payments under SSI and, if you are already receiving benefits, when we are deciding whether your disability continues. See §§ 404.1594, 416.424, 416.994, and 416.994a of our regulations. However, all of these different processes also include steps that consider whether your impairment meets or medically equals one of our listings.

What Are the Listings?

The listings are examples of impairments that we consider severe enough to prevent you as an adult from doing any gainful activity. If you are a child seeking SSI benefits based on disability, the listings describe impairments that we consider severe enough to result in marked and severe functional limitations. Although the listings are contained only in appendix 1 to subpart P of part 404 of our rules, we incorporate them by reference in the SSI program in § 416.925 of our regulations, and apply them to claims under both title II and title XVI of the Act.

How Do We Use the Listings?

The listings are in two parts. There are listings for adults (part A) and for children (part B). If you are an individual age 18 or over, we apply the listings in part A when we assess your claim, and we never use the listings in part B. If you are an individual under age 18, we first use the criteria in part B of the listings. If the listings in part B criteria do not apply, and the specific disease process(es) has a similar effect on adults

and children, we then use the criteria in part A. (See §§ 404.1525 and 416.925.)

If your impairment(s) does not meet any listing, we will also consider whether it medically equals any listing; that is, whether it is as medically severe. (See §§ 404.1526 and 416.926.)

What If You Do Not Have an Impairment That Meets or Medically Equals a Listing?

We use the listings only to decide that individuals are disabled or that they are still disabled. We will never deny your claim because your impairment(s) does not meet or medically equal a listing. If you are not working and you have a severe impairment(s) that does not meet or medically equal any listing, we may still find you disabled based on other rules in the sequential evaluation process that we use to evaluate all disability claims. Likewise, we will never decide that you no longer qualify for benefits because your impairment(s) does not meet or medically equal a listing.

Also, when we conduct reviews to determine whether your disability continues, we will not find that your disability has ended because we have changed a listing. Our regulations explain that, when we change our listings, we continue to use our prior listings when we review your case, if you qualified for disability benefits or SSI payments based on our determination or decision that your impairment(s) met or medically equaled the listings. In these cases, we determine whether you have experienced medical improvement, and if so, whether the medical improvement is related to the ability to work. If your condition(s) has medically improved so that you no longer meet or medically

equal the prior listing, we evaluate your case further to determine whether you are currently disabled. We may find that you are currently disabled, depending on the full circumstances of your case. See §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A). If you are a child who is eligible for SSI payments, we follow a similar rule when we decide whether you have experienced medical improvement in your condition(s). See § 416.994a(b)(2).

What Is ALS?

ALS, sometimes called Lou Gehrig's disease, is a progressive, invariably fatal neurological disease that attacks the nerve cells (motor neurons) responsible for controlling voluntary muscles.

ALS most commonly strikes people between 40 and 60 years of age. The diagnosis of ALS is based on history, clinical findings, and electrophysiological and neuroimaging studies. It is also arrived at by ruling out the existence of other neurological disorders that may have similar effects, such as neuropathy.

Eventually, all muscles under voluntary control are affected and individuals with ALS ultimately lose the ability to move their arms and legs, and the capacity to effectively swallow, speak, and breathe. Most people with ALS die from respiratory failure, usually within 3 to 5 years from the onset of symptoms. There is currently no cure for ALS.

What Did the Prior Listing for ALS Require?

The prior listing for ALS, listing 11.10, required that you have ALS with either:

- "Significant bulbar signs" (listing 11.10A) or
- "Disorganization of motor function as described in 11.04B" (listing 11.10B).

"Significant bulbar signs" include difficulty in the ability to chew, swallow, and speak. Listing 11.04B requires "[s]ignificant and persistent disorganization of motor function in two extremities, resulting in sustained disturbance of gross and dexterous movements, or gait and station"; in other words, inability to use both of your upper extremities effectively or to walk effectively.

Why Are We Revising the Listing for ALS?

We are revising listing 11.10 because we have determined that it is not necessary to include the requirements in paragraphs A and B of prior listing 11.10. We expect that these final rules will simplify and expedite our

adjudication of claims filed by individuals with ALS.

We receive very few applications based on ALS, and we approve almost all of them at the first level of our decisionmaking process. For example, in calendar year 2002 we received a total of only 1,384 claims based on ALS under titles II and XVI, and the State agencies that review disability claims for us allowed 1,324, or almost 96 percent of them, at the initial level of our administrative review process. The vast majority of the people who appealed their initial determinations denying their claims were also found disabled. In 2002, the State agencies found disabled about 80 percent of the people with claims based on ALS who asked for a reconsideration of their initial determinations. There were similar approval rates for every year since 1999.

There has also been significant Congressional action to help people with ALS qualify for benefits and services as quickly as possible. For example, in 2000, Congress amended the Act to provide that people who are disabled with ALS do not have to wait until they have received benefit payments under title II for 24 months before they can qualify for Medicare, as do all other people who are entitled to disability benefits under title II. See section 226(h) of the Act. These rules will help some people who are disabled with ALS to qualify for Medicare sooner.

We have decided that the simplest and fastest way to process claims of individuals with ALS without sacrificing the quality of our disability determinations and decisions is to revise the listing to provide that anyone who shows that he or she has ALS, established by clinical and laboratory findings, will be found disabled.

Why Are We Adding ALS to § 416.934 of Our Regulations?

The Act and our regulations provide that we may make SSI payments to you for up to 6 months on the basis of presumptive disability before we make a formal determination about whether you are disabled. You must also meet all other eligibility requirements before we may make presumptive disability payments. See section 1631(a)(4) of the Act and § 416.932 of our regulations. (There are no provisions in the Act that would allow us to make presumptive disability payments under title II.) Under § 416.933 of our regulations, we explain that we make these payments if there is a high degree of probability that we will find that you are disabled when we make our formal determination. If

our formal determination is that you are not disabled, the Act provides that you do not have to pay us back.

We may make findings of presumptive disability with or without medical evidence. Section 416.934 of our regulations provides a list of "specific impairment categories" that we use to find presumptive disability without medical evidence. For example, we may make a finding of presumptive disability without medical evidence based on an allegation of Down syndrome. A person meets a listing for Down syndrome (10.06 or 110.06) simply by showing medical evidence establishing that he or she has non-mosaic Down syndrome. Therefore, there is a high degree of probability that we will find people who allege Down syndrome disabled. The new rules for ALS are similar. There is a high degree of probability that we will find people who have ALS disabled when we make our formal determination because everyone who applies for SSI and who has medical evidence showing that they have ALS will be found disabled under revised listing 11.10.

When Will We Start To Use These Final Rules?

We will apply the final rules starting today.

As is our usual practice when we make changes to our regulations, we will apply these final rules to the claims of applicants for benefits that are pending at any stage of our administrative review process, including any claims that are pending administrative review after remand from a Federal court.

What Revisions Are We Making?

We are adding a new section 11.00G to the introductory material in the neurological body system section of our listings. The new section contains three paragraphs. Section 11.00G1 provides some basic information about ALS. Sections 11.00G2 and 11.00G3 provide information about how ALS is diagnosed and the information we need to establish that you meet the requirements of revised listing 11.10. The language of paragraphs 11.00G2 and 11.00G3 is based on language we use in the introductory material to the Down syndrome listings (sections 10.00A and B, and 110.00A and B) and the introductory material to our immune system listings regarding documentation of HIV infection (sections 14.00D and 114.00D).

We are revising listing 11.10 to provide that, if you have a diagnosis of ALS established by the medical evidence described in section 11.00G,

we will find that you are disabled. We are not adding a corresponding listing in part B of our listings, the listings we use to evaluate people who are under 18 years old, because ALS is rare in children. We will use revised listing 11.10 to evaluate all people with ALS, including people who are under age 18, as we did under the prior listing.

As already noted, we are also adding a new paragraph (i) to § 416.934 to allow us to make findings of presumptive disability without medical evidence in cases involving allegations of ALS. Together with this addition, we are also making minor editorial changes for context and to update one of our rules. We needed to revise paragraph (g) near the end of prior § 416.934 to remove the word "and" at the end of the section because paragraph (h) is no longer the last paragraph in the section. In addition, we are changing the language of paragraph (g) from "Allegation of Down's syndrome (Mongolism)" to "Allegation of Down syndrome." This is the current terminology for the condition.

Regulatory Procedures

Pursuant to section 702(a)(5) of the Act, 42 U.S.C. 902(a)(5), the Social Security Administration follows the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 in the development of its regulations. The APA provides exceptions to its Notice of Proposed Rulemaking (NPRM) procedures when an agency finds that there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. In the case of these rules, we have determined that, under 5 U.S.C. 553(b)(B), good cause exists for waiving the NPRM procedures.

As we have noted above, we receive very few claims each year based on ALS. In light of the nature of ALS, we find disabled at the initial level of our administrative review process about 96 percent of people who apply for disability benefits under title II and title XVI based on the condition. Many of the remaining few people whose claims are denied initially are found disabled on appeal. Ultimately, we find that almost all people who apply based on ALS are disabled. We expect that the changes we are making in these rules will simplify and expedite our processing of claims based on ALS. The main differences between these rules and our prior rules are that a small number of people who would be required to appeal an unfavorable determination under our prior rules will no longer have to do so, and a very small number of people

whose claims were denied incorrectly under our prior rules will now properly be found to be disabled. Consequently, we find that prior notice and comment is unnecessary with respect to these rules.

We also find that good cause exists for waiving the APA's notice-and-comment rulemaking procedures because use of notice-and-comment rulemaking procedures would be contrary to the public interest. In light of the serious consequences caused by ALS, ultimately, we find that almost all people who apply for disability benefits based on the condition are disabled. The serious consequences caused by ALS are also reflected in Congress' judgment, set out in section 226(h) of the Act, to eliminate for individuals who are disabled with ALS the normal 24-month Medicare waiting period that applies to people who are found disabled under title II of the Act. The changes we are making in these rules will allow us to make more timely determinations of disability for individuals with a progressive and invariably fatal disorder. The changes we are making in these rules will also help to implement Congress' judgment that individuals who are disabled under title II of the Act based on ALS should also receive immediate entitlement to Medicare rather than having to wait 24 months. It is critical that we issue these rules as soon as possible so that more people can qualify as quickly as possible for Medicare benefits and other services. Likewise, the small number of individuals who file applications for SSI will be able to benefit from the presumptive eligibility provisions of these rules. For these reasons, we find that use of the APA's notice-and-comment rulemaking procedures is contrary to the public interest in this instance.

In addition, we find good cause for dispensing with the 30-day delay in the effective date of a substantive rule, as provided for by 5 U.S.C. 553(d)(3). For the reasons that we have discussed above, we find that it is in the public interest to make these rules effective upon publication.

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these final rules meet the criteria for a significant regulatory action under Executive Order 12866, as amended by Executive Order 13258. Thus, they were subject to OMB review.

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 rules contain reporting requirements at sections 11.00G and 11.10. The public reporting burden is accounted for in the Information Collection Requests for the various forms that the public uses to submit the information to SSA. Consequently, a 1-hour placeholder burden is being assigned to the specific reporting requirement(s) contained in these rules. We are seeking clearance of the burden referenced in these rules because the rules were not considered during the clearance of the forms. An Information Collection Request has been submitted to OMB. We are soliciting comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. Comments should be submitted to the Office of Management and Budget at the following fax number and to the Social Security Administration at the following address or fax number:

Office of Management and Budget, Attn:
Desk Officer for SSA, Fax Number:
202-395-6974.

Social Security Administration, Attn:
SSA Reports Clearance Officer, 1338
Annex Building, 6401 Security
Boulevard, Baltimore, MD 21235-
6401, Fax Number: 410-965-6400.

Comments can be received for between 30 and 60 days after publication of this notice and will be most useful if received by SSA within 30 days of publication.

(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; and 96.006, Supplemental Security Income)

List of Subjects

20 CFR Part 404

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

20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Reporting and recordkeeping

requirements, Supplemental Security Income.

Dated: July 22, 2003.

Jo Anne B. Barnhart,
Commissioner of Social Security.

■ For the reasons set forth in the preamble, subpart P of part 404 of 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—)

■ 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.

Appendix 1 to Subpart P of Part 404— [Amended]

■ 2. Add new section 11.00G to section 11.00 in part A of appendix 1 and revise section 11.10 to read as follows:

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

* * * * *

11.00 Neurological

* * * * *

G. *Amyotrophic Lateral Sclerosis (ALS)*. 1. Amyotrophic lateral sclerosis (ALS), sometimes called Lou Gehrig's disease, is a progressive, invariably fatal neurological disease that attacks the nerve cells (motor neurons) responsible for controlling voluntary muscles. Eventually, all muscles under voluntary control are affected, and individuals with ALS ultimately lose their ability to move their arms and legs, and their capacity to swallow, speak, and breathe. Most people with ALS die from respiratory failure. There is currently no cure for ALS, and most treatments are designed only to relieve symptoms and improve the quality of life.

2. Diagnosis of ALS is based on history, neurological findings consistent with the diagnosis of ALS, and electrophysiological and neuroimaging testing to rule out other impairments that may cause similar signs and symptoms. The diagnosis may also be supported by electrophysiological studies (electromyography or nerve conduction studies), but these tests may be negative or only suggestive of the diagnosis. There is no single test that establishes the existence of ALS.

3. For purposes of 11.10, documentation of the diagnosis must be by generally accepted methods consistent with the prevailing state of medical knowledge and clinical practice. The evidence should include documentation of a clinically appropriate medical history, neurological findings consistent with the diagnosis of ALS, and the results of any

electrophysiological and neuroimaging testing.

* * * * *

11.10 *Amyotrophic lateral sclerosis* established by clinical and laboratory findings, as described in 11.00G.

* * * * *

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

■ 3. 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).

■ 4. In § 416.934, revise paragraph (g) and add new paragraph (i) to read as follows:

§ 416.934 Impairments which may warrant a finding of presumptive disability or presumptive blindness.

* * * * *

(g) Allegation of Down syndrome.

* * * * *

(i) Allegation of amyotrophic lateral sclerosis (ALS, Lou Gehrig's disease).

[FR Doc. 03–22016 Filed 8–27–03; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2003N–0346]

Food Labeling: Ingredient Labeling of Dietary Supplements That Contain Botanicals

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulation on declaring botanical ingredients in dietary supplements to incorporate by reference the latest editions of two books. Currently, the regulation incorporates by reference *Herbs of Commerce* (1992) and the *International Code of Botanical Nomenclature (Tokyo Code) 1994*. FDA is replacing the references to these editions with the 2000 editions of the same books. This action is intended to provide industry with current and more comprehensive references to use in

identifying on product labels the common or usual name of each botanical ingredient contained in dietary supplements. In addition, FDA is incorporating new statutory restrictions on the use of the word “ginseng” in dietary supplement labeling. Finally, FDA is making minor wording changes in its regulation on declaring botanical ingredients in dietary supplements. These changes are intended to improve the reader's understanding, consistent with the principles of plain English, or to be more technically accurate, consistent with internationally accepted botanical terminology. FDA is issuing a direct final rule for this action because FDA expects there will be no significant adverse comments on the rule. Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule through the usual notice-and-comment rulemaking process. If FDA receives significant adverse comment on either rule, FDA intends to withdraw the direct final rule and proceed with the rulemaking. The companion proposed rule and direct final rule are substantively identical.

DATES: This rule is effective January 1, 2006. Submit written or electronic comments on this direct final rule by November 12, 2003. If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document in the **Federal Register** confirming the effective date of this direct final rule. If the agency receives any timely significant adverse comments, FDA intends to publish a document in the **Federal Register** withdrawing this direct final rule before its effective date. 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 101.4(h) as of January 1, 2006.

ADDRESSES: Submit written comments on this direct final rule to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Victoria Lutwak, Office of Nutritional Products, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2375.

SUPPLEMENTARY INFORMATION: