The new part 321 provides that both an application and claims for benefits under the Railroad Unemployment Insurance Act may be filed electronically through the Board's Internet Web site utilizing a User ID and a PIN/Password system. The new part further provides that determinations regarding those applications and claims will be adjudicated in accord with established procedures.

In establishing the authenticity of the person who is filing an application or claim for benefits, the Board intends to use a User ID and a PIN/Password system for identification as a substitute for a signature.

The Board currently uses a User ID and a PIN/Password system to allow employers access to RRBLINK to make electronic tax deposits and submit Form DC–1, ''Employer's Quarterly Report of Contributions Under the RUIA'' (Railroad Unemployment Insurance Act) electronically. A PIN/Password system is used to access the Pay.gov Web site. The U.S. Department of the Treasury operates the Pay.gov Web site. Such a system is also consistent with the guidance provided by the Department of Justice regarding the use of electronic processes.

The Board published part 321 as a proposed rule on November 7, 2003 (68 FR 63041). Only one comment was received. The commenter found the reference to the ''User ID/PIN/Password system'' confusing. In this final rule publication we have clarified that the person will be identified by a User ID and a PIN that will serve as the password to make transactions through the system.

The Board, with the concurrence of the Office of Management and Budget, has determined that this final rule does not constitute a significant regulatory action under Executive Order 12866. Therefore, no regulatory analysis is required. The Office of Management and Budget has approved information collections associated with this rule under control numbers 3220–0022, 3220–0039, and 3220–0198.

List of Subjects in 20 CFR Part 321

Claims, Railroad unemployment insurance, Reporting and recordkeeping requirements.

■ For the reasons set out in the preamble, the Railroad Retirement Board amends title 20, chapter II, of the Code of Federal Regulations by adding a new part 321 to read as follows:

PART 321—ELECTRONIC FILING OF APPLICATIONS AND CLAIMS FOR BENEFITS UNDER THE RAILROAD UNEMPLOYMENT INSURANCE ACT

Sec.
321.1 Filing applications electronically.
321.2 Filing claims for benefits electronically.

Authority: 45 U.S.C. 355 and 362(l).

§ 321.1 Filing applications electronically.

(a) *Electronic filing.* An application for benefits under the Railroad Unemployment Insurance Act may be filed electronically through the Board's Internet Web site, *http://www.rrb.gov*, utilizing a User ID and a PIN/Password.

(b) *Adjudication of applications filed electronically.* An application filed electronically shall be adjudicated in accordance with the procedures set forth in this part.

(c) *Date of filing.* The date of filing for an application filed electronically shall be the date that the electronic filing of the application is accepted by the Board's electronic system. If an attempt to file an application through the Board's electronic system is unsuccessful and is rejected by that system, the claimant must submit another application. If the subsequent application, filed either electronically or on paper, is received by the Board within 30 days from the date of the notification that the initial filing attempt was rejected, the Board will establish the filing date of the subsequent application as the date the rejected application was attempted to be filed.

§ 321.2 Filing claims for benefits electronically.

(a) *Electronic filing.* A claim for benefits under the Railroad Unemployment Insurance Act may be filed electronically through the Board's Internet Web site, *http://www.rrb.gov*, utilizing a User ID and a PIN/Password.

(b) *Adjudication of claims filed electronically.* A claim for benefits under the Railroad Unemployment Insurance Act filed electronically shall be adjudicated in accordance with the procedures set forth in this part.

(c) *Date of filing.* The date of filing for a claim for benefits under the Railroad Unemployment Insurance Act filed electronically shall be the date that the electronic filing of the claim is accepted by the Board's electronic system. If an attempt to file a claim for benefits under the Railroad Unemployment Insurance Act is unsuccessful and is rejected by the Board's electronic system, the claimant must submit another claim for benefits. If the subsequent claim for benefits, either filed electronically or on paper, is received by the Board within 30 days from the date of the notification that the initial filing was rejected, the Board will establish the filing date of the subsequent claim as the date the rejected claim was attempted to be filed.

Dated: June 3, 2004.

By Authority of the Board.
For the Board,

Carolyn Rose,

Staff Assistant, Office of Secretary to the Board.

[FR Doc. 04–13009 Filed 6–8–04; 8:45 am]

BILLING CODE 7905–01–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Regulation No. 4]

RIN 0960–AF29

Revised Medical Criteria for Evaluating Skin Disorders

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 claims involving skin disorders. We apply these criteria when you claim benefits based on disability under title II and title XVI of the Social Security Act (the Act). The revisions reflect advances in medical knowledge, treatment, and methods of evaluating skin disorders.

DATES: These rules are effective July 9, 2004.

ADDRESSES: *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://policy.ssa.gov/pnpublic.nsf/LawsRegs.*

FOR FURTHER INFORMATION CONTACT: Suzanne DiMarino, Social Insurance Specialist, Office of Regulations, Social Security Administration, 100 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 965–1769 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/.*

SUPPLEMENTARY INFORMATION: We are revising and making final the rules we proposed in the Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on December 10, 2001

(66 FR 63634). We provide a summary of the provisions of the final rules below, with an explanation of the changes we have made from the text in the NPRM. We then provide a summary of the public comments and our reasons for adopting or not adopting the recommendations in the summaries of the comments in the section, ''Public Comments.'' The final rule language follows the comment section.

What Programs Do These Final Rules Affect?

These final rules 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 rules 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 Supplemental Security Income (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, 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 can be 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. Do you have the residual functional capacity to do your past relevant work? If you do, we will find that you are not disabled. If you do not, we will go on to step 5.

5. Does your impairment(s) prevent you from doing any other work that exists in significant numbers in the national economy, 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 a different sequential evaluation process for children who apply for payments based on disability under SSI. If you are already receiving benefits, we also use a different sequential evaluation process when we decide whether your disability continues. See §§ 404.1594, 416.924, 416.994, and 416.994a of our regulations. However, all of these processes include steps at which we 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 regulations, 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 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.'' Likewise, we will never

decide that your disability has ended only 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 a listing. 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).

Why Are We Revising the Listings for Skin Disorders?

We are revising the listings to update their medical criteria and to provide more information about how we evaluate skin disorders. We last published final rules containing comprehensive revisions to the skin disorder listings in the **Federal Register** on March 27, 1979 (44 FR 18170). In subsequent rules published on December 6, 1985 (50 FR 50068), we indicated that due to advances in medical treatment, technology, and program experience we would periodically review and update the listings. We published the latest extension for part A of the skin disorders listings, until July 1, 2005, in the **Federal Register** on June 20, 2003 (68 FR 36911).

When Will We Start To Use These Final Rules?

We will start to use these final rules on their effective date. We will continue to apply the prior rules until the effective date of these final rules. When the final rules become effective, we will apply them to new applications filed on or after the effective date of these rules.

As is our usual practice when we make changes to our regulations, we will apply these final rules on or after their effective date when we make a determination or decision in claims for benefits that are pending in our administrative review process, including those claims that are pending administrative review after remand to us from a Federal court. With respect to claims in which we have made a final decision, and that are pending judicial review in Federal court, we expect that the court's review of the Commissioner's final decision would be made in accordance with the rules in effect at the time of the final decision. If the court determines that the Commissioner's final decision is not supported by substantial evidence, or contains an error of law, we would expect that the court would reverse the final decision and remand the case for further administrative proceedings pursuant to the fourth sentence of section 205(g) of the Act, except in those few instances in which the court determines that it is appropriate to reverse the final decision and award benefits without remanding the case for further administrative proceedings. In those cases decided by a court after the effective date of the rules, where the court reverses the Commissioner's final decision and remands the case for further administrative proceedings, on remand, we will apply the provisions of these final rules to the entire period at issue in the claim.

What Do We Mean by ''Final Rules'' and ''Prior Rules''?

Even though these rules will not go into effect until 30 days after publication of this notice, for clarity we refer to the changes we are making here as the ''final rules'' and to the rules that will be changed by these final rules as the ''prior rules.''

How Long Will These Final Rules Be Effective?

These final rules will no longer be effective 8 years after the date on which they become effective, unless we extend them, or revise and issue them again.

What Revisions Are We Making With These Final Rules?

We are:

- Revising the headings of the listings to put them in plain language;
- Revising the order of the listings and updating the diagnostic groupings to more logically group skin disorders;
- Adding listings for xeroderma pigmentosum and other genetic photosensitivity disorders;
- Adding a new listing for burns that do not meet the requirements of listing 1.08;
- Providing a more uniform and clearly defined statement of severity required for a listing-level skin disorder;
- Expanding the guidance in the introductory text to the listings;
- Making nonsubstantive editorial changes to the prior listings and introductory text; and
- Adding a skin disorders body system in part B of appendix 1 to provide a set of childhood skin disorder listings.

How Are We Changing the Introductory Text to the Adult Skin Disorder Listings?

We are changing the heading from 8.00 Skin to 8.00 Skin Disorders. We are expanding and reorganizing the introductory text to the skin disorders listings in prior 8.00A and 8.00B to provide additional guidance in applying the skin disorders listings. In doing so, we are:

- Expanding and supplementing the first sentence of prior 8.00A and moving it into final 8.00C;
- Expanding and supplementing the second sentence of prior 8.00A and moving it into final 8.00C2 and 8.00G;
- Expanding the third sentence of prior 8.00A and moving it into final 8.00C4; and
- Expanding the material in 8.00B and moving it into final 8.00D.

8.00A—What Skin Disorders Do We Evaluate With These Listings?

This new section describes the kinds of skin disorders we evaluate under these listings.

8.00B—What Documentation Do We Need?

We are adding a new section that discusses the documentation we require when we evaluate the existence and severity of skin disorders. The section explains the information we expect to find in a complete dermatologic case record in order to assess the existence and severity of your impairment. It also explains that we may need laboratory findings or evidence from other medically acceptable methods consistent with the prevailing state of medical knowledge and clinical practice to confirm your diagnosis. In a nonsubstantive editorial revision, we clarified the language of the NPRM to explain that these are considerations we make whenever we assess the severity of skin disorders.

8.00C—How Do We Assess the Severity of Your Skin Disorder(s)?

This section, which is partially new and partially based on the first sentence of prior 8.00A, explains four factors that

we consider whenever we evaluate the severity of skin disorders. The section consists of four subsections.

Final section 8.00C1 defines extensive skin lesions. ''Extensive'' is a term we use in most of the final listings. We explain that the term ''extensive'' means lesions that involve multiple body sites or critical body areas and that result in ''a very serious limitation,'' a term we use to define an extreme limitation for purposes of determining listing-level severity in other regulations. Because extensive skin lesions result in a very serious limitation, we will often be able to determine whether your lesions meet the requirement of these listings based on the medical evidence in your case record, without the need to develop additional evidence about your ability to perform the specific activities in the examples set out in final sections 8.00C1a, C1b, and C1c.

We changed the phrase ''very serious limitations'' from the NPRM to ''a very serious limitation'' in response to a comment we describe below. We also made a number of editorial changes from the language of the NPRM to clarify our intent. For example, we removed the phrase ''sufficient surface area'' which we proposed in section 8.00C1 of the NPRM, because it was not specific and was unnecessary to the meaning of the sentence. Lesions that result in a very serious limitation are by definition of sufficient surface area to do so. In the examples, we also added the word ''both'' in front of the words ''hands,'' ''feet,'' and ''inguinal areas'' to be even clearer about our intent.

Final section 8.00C2 is a new section we added in response to comments that asked us to explain how we evaluate skin conditions that produce lesions that do not persist for at least 3 months but are subject to frequent flareups.

Final section 8.00C3, which was section 8.00C2 in the NPRM, explains that we evaluate symptoms (including pain) consistent with our rules in §§ 404.1528, 404.1529, 416.928, and 416.929. We revised this section to correct a technical error in the cross-references we used in the NPRM.

Final section 8.00C4, which was proposed section 8.00C3 in the NPRM, explains that while skin disorders frequently respond to treatment, there is a wide variation in how people respond to treatment, and that some impairments become resistant to treatment. We also note that treatment can have side effects that in themselves result in limitations. Therefore, we consider each case on an individual basis. In response to a comment, we added a reference to final section 8.00H in final section 8.00C4b to remind our adjudicators how to assess situations in which there is no treatment or in which treatment has not lasted for 3 months.

8.00D—How Do We Assess Impairments That May Affect the Skin and Other Body Systems?

This section revises prior section 8.00B. We are clarifying that other impairments besides the systemic ones we included in prior section 8.00B can involve the skin, and we explain how we evaluate such impairments under the listings. We are also expanding the list of examples of impairments that may affect the skin and other body systems.

In the final rules, we revised the heading of this section and reorganized its text for clarity. For example, we combined proposed sections 8.00D3 and 8.00D4 in final section 8.00D3 because both proposed sections addressed connective tissue and other immune system disorders. In response to a comment, we added a reference to Sjögren's syndrome in the examples of connective tissue disorders and other immune disorders we include in parentheses in the heading of final section 8.00D3. We redesignated section 8.00D5 and 108.00D5 in the NPRM, which addressed disfigurement and deformity, to 8.00D4 and 108.00D4 in the final rules.

8.00E—How Do We Evaluate Genetic Photosensitivity Disorders?

Final section 8.00E is another new section. It explains how we evaluate xeroderma pigmentosum (XP) and other genetic photosensitivity disorders. We added it in response to comments that said the proposed listings did not make allowance for individuals with XP who do not have extensive skin lesions because they live an extremely restricted lifestyle in order to avoid or minimize serious consequences of the impairment. Because we agreed with the commenters, we added a new listing 8.07A, which provides that we will consider disabled any person who has a diagnosis of XP confirmed by clinical and laboratory findings. We also added a separate listing 8.07B for individuals who have other kinds of genetic photosensitivity disorders. We describe these listings in more detail later in this preamble.

Final section 8.00E provides more information about XP and other genetic photosensitivity disorders. It also explains how we apply the new listings and includes a definition of the term, ''inability to function outside of a highly protective environment,'' the severity criterion we use in final listing 8.07B2. In final section 8.00E3, we explain our criteria for the clinical and laboratory findings we need to establish the existence of XP or another genetic photosensitivity disorder. Final section 8.00E3 is based on section 10.00B of our listings, a provision that explains the evidence we need to confirm a diagnosis of Down syndrome, another kind of genetic disorder. Like that section, final section 8.00E3 explains that we need both clinical evidence and evidence of definitive genetic laboratory testing. However, in recognition of the fact that in many cases laboratory testing may have been conducted years in the past, we provide that we do not need a copy of the actual laboratory report if we have medical evidence that is persuasive that a positive diagnosis has been confirmed by laboratory testing in the past.

Because we added this new section 8.00E, we redesignated proposed section 8.00E as final section 8.00F.

8.00F—How Do We Evaluate Burns?

Final section 8.00F was proposed section 8.00E in the NPRM. We include this new section on burns in the introductory text to the skin disorder listings in response to many inquiries we have received over the years about how to evaluate these injuries.

In response to a comment, we added a new listing 8.08 for evaluating burns that do not meet the criteria of listing 1.08. As a consequence, we revised the language we proposed for this section of the introductory text to reflect this change. We also revised the language of this section to explain more clearly that we evaluate burns the way we evaluate other disorders that can affect both the skin and other body systems; that is, by referring first to the listing for the predominant feature of the impairment.

For consistency, we are also adding a sentence to section 1.00M in the musculoskeletal body system that cross-refers to final section 8.00F. This paragraph in the musculoskeletal listings defines the term ''under continuing surgical management'' for purposes of listing 1.08. The sentence we are adding explains that when burns are not under continuing surgical management, our adjudicators should refer to section 8.00F.

8.00G—How Do We Determine if Your Skin Disorder(s) Will Continue at a Disabling Level of Severity in Order To Meet the Duration Requirement?

We are adding this section to explain how we determine if your impairment(s) meets the duration requirement. This section is partially new and partially based on the second sentence of prior section 8.00A. We revised the language from the NPRM to more clearly state our

intent. This is not a substantive change from the NPRM, only a clarification of the proposed language.

In the final rules, we explain that in most of these final listings we will find that your impairment meets the duration requirement if you have a skin disorder with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed. We explain that by ''persist,'' we mean that the longitudinal clinical record shows that, with few exceptions, the lesions have been at the level of severity specified in the listing.

We also explain how we consider whether your impairment meets the duration requirement under listings 8.07 and 8.08, the listings that do not include the 3-month criterion. As we have already noted, under listing 8.07A, we presume that you meet the duration requirement if you have XP, established by the clinical and laboratory findings described in 8.00E. For listings 8.07B and 8.08, you must show that your limitations have lasted or can be expected to last for a continuous period of at least 12 months. Therefore, we explain in final section 8.00G that we will decide whether your skin disorder satisfies the duration requirement under these listings by considering all of the relevant medical and other information in your case record.

8.00H—How Do We Assess Your Skin Disorder(s) if Your Impairment Does Not Meet the Requirements of One of These Listings?

This new section explains how we assess a skin disorder(s) when you do not have continuing treatment as prescribed, when your treatment has not lasted for at least 3 months, or when you do not have extensive skin lesions that have persisted for at least 3 months.

In the final rules, we are making changes in response to public comments about this section and to reflect other changes we are making in these final rules. We are also making nonsubstantive editorial changes for clarity and correcting an error in the NPRM. We explain that your impairment cannot meet the requirements of most of these listings unless you have extensive skin lesions that have persisted for at least 3 months despite continuing treatment as prescribed; however, we may still find that you are disabled based on our other rules for determining disability. In the final rules, we indicate that final listings 8.07 and 8.08 are exceptions to this general rule. In final listing 8.08, we do require evidence of extensive skin lesions, but do not require evidence of 3 months of continuing treatment as prescribed because we believe that it will be evident from the extent of the burns whether extensive lesions can be expected to last for a continuous period of at least 12 months.

We also deleted the reference to our policy regarding failure to follow prescribed treatment, which we had included in proposed section 8.00G1 of the NPRM. The reference was inappropriate in this context and could have been confusing. Under our policy, failure to follow prescribed treatment is a basis for denying a claim for benefits and does not apply when we consider whether you meet the requirements of a listing.

How Are We Proposing To Change the Criteria in the Listings for Evaluating Skin Disorders in Adults?

8.01—Category of Impairments, Skin Disorders

Most of the changes we are making in these final skin disorder listings:

- Update medical terminology,
- Clarify our criteria,
- Include more skin disorders in each category, and
- Reorganize the prior listings.

We are also adding final listings 8.07A and B for photosensitivity disorders and final listing 8.08 for burns. Under the prior listings, these disorders were not listed and could therefore only be found to medically equal a listing, such as a skin or musculoskeletal disorder listing, if they were of listing-level severity. We are also revising the requirement in most of the prior skin disorders listings for extensive lesions ''not responding to prescribed treatment'' with the more specific requirement that there be extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

The following is a detailed explanation of the revised listing criteria.

Listing 8.02—Ichthyosis

We are revising the heading of listing 8.02 to cover the general group of disorders characterized by noninflammatory scaling of the skin. The prior listing named three specific kinds of disorders. The final listing includes all forms of ichthyosis. We are also moving exfoliative dermatitis from prior listing 8.02 to final listing 8.05, where it will be evaluated with the other dermatitis disorders.

Listing 8.03—Bullous Disease

We are revising the heading of listing 8.03 so that we can apply it to all types of bullous diseases. We are citing as examples four diseases we included in the prior listings and adding epidermolysis bullosa as a fifth example. We include dermatitis herpetiformis in this listing instead of listing 8.05 because, despite the word ''dermatitis'' in its name, dermatitis herpetiformis is primarily a bullous disease.

Listing 8.04—Chronic Infections of the Skin or Mucous Membranes

We are revising the heading of listing 8.04 so that it will include infections other than deep mycotic (fungal) infections. In this listing, similarly to the prior listing, we use the words ''fungating'' (to grow exuberantly like a fungus or spongy growth) and ''ulcerating'' (a lesion through the skin or a mucous membrane resulting from loss of tissue, usually with inflammation) to modify the term ''extensive skin lesions'' because they are descriptive of the different types of lesions frequently associated with the more severe types of chronic skin infections. Listing-level severity is characterized by either extensive fungating or extensive ulcerating lesions that persist for at least 3 months despite continuing treatment as prescribed.

Listing 8.05—Dermatitis

We are revising the heading of listing 8.05 so that we can also use it to evaluate miscellaneous inflammatory conditions of the skin, rather than just the three conditions the prior listing cited (psoriasis, atopic dermatitis, and dyshidrosis). We will use the revised listing to evaluate all dermatitis disorders, including environmental skin conditions such as allergic contact dermatitis, which we have added to the list of examples of impairments covered by this listing. As already noted, we are also including exfoliative dermatitis under this listing instead of including it under listing 8.02.

Listing 8.06—Hidradenitis Suppurativa

We are removing the reference to acne conglobata from listing 8.06 because it frequently responds well to treatment. Therefore, we cannot assume that it will meet the duration requirement. We are also providing the same severity standard for hidradenitis suppurativa as for most of the other listings in these final rules. The condition must result in extensive skin lesions, as defined in final section 8.00C1, that persist despite at least 3 months of continuing treatment as prescribed. The lesions must involve both axillae, both inguinal areas or the perineum. We deleted the reference to surgical treatment from the prior listing because the phrase

''continuing treatment as prescribed'' includes surgical treatment. As we did in final section 8.00C1, we added the word ''both'' in front of the words ''axillae'' and ''inguinal areas'' to be clearer about our intent.

Listing 8.07—Genetic Photosensitivity Disorders

We are adding a listing for evaluating photosensitivity disorders, including xeroderma pigmentosum (XP), in adults. Some individuals with these disorders are now surviving into adulthood, and we believe it is appropriate to have separate listings for them.

In the NPRM, we proposed a listing for photosensitivity disorders, such as XP, that used the same criteria as the other proposed listings: extensive lesions that persist for at least 3 months despite prescribed treatment. Some commenters pointed out that very few people with XP could meet the criteria of the proposed listing because many people with the disorder live very restricted lifestyles to avoid consequences like extensive lesions. In reviewing these comments and reconsidering our proposed listing, we determined that XP is such a serious disorder that we could conclude that any person who has XP would be very seriously limited, given the likelihood that he or she would need to be in a highly protective environment to avoid the serious consequences of the disorder. Indeed, two of the commenters described this precise situation. Moreover, XP is a lifelong disorder that does not improve, so we could conclude that any person who has XP would meet the duration requirement. Therefore, we provide in final listing 8.07A that individuals who have XP that is confirmed by clinical and laboratory findings are disabled from birth.

In final listing 8.07B, we provide criteria for evaluating other genetic photosensitivity disorders. XP is only an example of the kind of photosensitivity disorders we intended to include in proposed listing 8.07A; that is, what physicians call ''heritable'' photosensitivity disorders, and what we call ''genetic'' photosensitivity disorders in these listings. In considering other types of genetic photosensitivity disorders, we determined that these other disorders can have unpredictable courses where skin lesions improve and a highly protective environment may not be required. Therefore, to meet this listing you must show that your genetic photosensitivity disorder results in extensive lesions or that you are unable to function outside of a highly protective environment. You must also show that these limitations have lasted or can be expected to last for a continuous period of at least 12 months.

Listing 8.08—Burns

In response to a comment, we are adding a listing for evaluating burns that do not meet the criteria of listing 1.08 in our musculoskeletal listings. Listing 1.08 applies to individuals who have soft tissue injuries, including burns, that are under continuing surgical management (as defined in 1.00M in the introductory text to the musculoskeletal listings) directed toward the salvage or restoration of major function of an extremity, the trunk, or the face and head, and in which such salvage or restoration was not achieved or expected to be achieved within 12 months of onset. Under the prior listings, we used our policy of medical equivalence to evaluate individuals whose burns did not meet listing 1.08. Generally we used our medical equivalence policy to evaluate claims by individuals who had achieved maximum benefit from surgical management or whose burns did not satisfy one of the requirements of the listing.

Your impairment will meet this listing if you have extensive skin lesions, as defined in final section 8.00C1, that have lasted or that can be expected to last for a continuous period of at least 12 months. We explain our reasons for making this change in more detail in the public comments section of this preamble.

Why Are We Adding Listings for Evaluating Skin Disorders in Children?

We are adding new listings to evaluate claims of individuals under age 18 who have skin disorders to maintain consistency with the other body system listings, which have both adult and child criteria.

How Do the Final Skin Disorder Listings for Children Differ From the Final Adult Listings?

The skin disorder listings for children are essentially identical to those for adults. Exceptions are in final sections 108.00D5 and D6, where we include examples of erythropoietic porphyrias and hemangiomas for children.

We mention these disorders only in the introductory text in part B because the skin manifestations of these disorders are not likely to be the primary manifestations in adults. For example, a major symptom in children who have erythropoietic porphyria, a metabolic disorder characterized by a deficiency of the enzyme ferrochelatase that is essential to the synthesis of hemoglobin, is hypersensitivity of skin to sunlight and some types of artificial light. Generally, by adulthood, anemia is a prominent manifestation in the more severe cases, with possible complications related to liver and gallbladder function. Therefore, we evaluate the impairment in adults under the appropriate body systems for those manifestations, the hemic and lymphatic system (7.00) and the digestive system (5.00). Similarly, most hemangiomas disappear spontaneously or are surgically removed in childhood. When hemangiomas are associated with Kasabach-Merritt Syndrome, a condition in which the low number of blood platelets causes bleeding, the hematologic manifestations are obvious in adults and we evaluate them under the listings in the hemic and lymphatic system, sections 7.00.

The rules in part B are also slightly different from the rules in part A to reflect differences between the rules for evaluating disability in children under the SSI program and the rules for evaluating disability in adults. For example, instead of referring to the ''inability to do any gainful activity,'' we refer to the standard for childhood disability, ''marked and severe functional limitations.'' Likewise, instead of referring to residual functional capacity assessments and the last step of the five-step adult sequential evaluation process, we refer to the policy of functional equivalence.

Other Changes

Throughout these final rules, we are making nonsubstantive editorial changes from the language we proposed in the NPRM. The changes:

- Make the language clearer and simpler;
- Improve the consistency between parts A and B of the skin disorders listings;
- Improve the consistency between the skin disorders listings and other body system listings; and,
- Correct technical errors that were in the NPRM.

For example, in these final rules, we changed the term ''skin impairments,'' which we used in the introductory text in the NPRM, to ''skin disorders.'' We also changed the phrase ''prescribed treatment'' in the NPRM to ''continuing treatment as prescribed'' wherever it appeared. In the NPRM we used both phrases inconsistently and now we are using the same phrase everywhere throughout these final rules. We have already given examples of several of the other changes in the explanation of changes above.

Public Comments

We published these rules in the **Federal Register** as an NPRM on December 10, 2001 (66 FR 63634). We gave members of the public a period of 60 days in which to comment. The comment period ended on February 8, 2002.

We received a total of 12 letters, telefaxes, and e-mails responding to our request for comments. The comments came from a professional medical organization, advocacy organizations for specific types of skin disorders and other disorders that may involve the skin, legal advocates, parents of children with skin disorders, and a State agency that makes disability determinations for us. We carefully considered all of the comments, and we are making a number of changes in these final rules as a result of the comments.

Some of the comment letters were long and detailed, requiring us to condense, summarize, or paraphrase them. We have tried to present all views and to respond to all of the significant issues raised by the commenters. We provide our reasons for adopting or not adopting the comments in our responses below.

Final Sections 8.00D and 108.00D—How Do We Assess Impairments That May Affect the Skin and Other Body Systems?

Comment: We received two comments about facial disfigurement. One commenter discussed the social difficulties an individual with a facial disfigurement may encounter in school and in finding a job. Another commenter mentioned the difficulties that can result if frequent surgeries or other medical attention is needed to care for or correct the disfigurement. The first commenter encouraged us to make the changes needed to help these individuals.

Response: We agree with the commenters that facial disfigurement can be a cause of significant physical and mental limitations. This is why we proposed new sections 8.00D5 and 108.00D5 in the NPRM to address the complications of facial disfigurement and its psychological effects. (In the final rule, we redesignated these sections as 8.00D4 and 108.00D4.) The final provisions explain that disfigurement may have specific physical effects, such as loss of sight, hearing, speech, and the ability to chew, but may also have effects that we evaluate under the mental disorders listings, such as when they affect mood or social functioning. We evaluate the physical and mental effects of disfigurement under the appropriate listings for the manifestations; for example, special senses and speech, 2.00 and 102.00, the digestive system, 5.00 and 105.00, and mental disorders, 12.00 and 112.00. In addition, we explain in final sections 8.00C4 and 108.00C4 (proposed sections 8.00C3 and 108.00C3) that we consider the effects of surgery when we evaluate the severity and duration of your impairment. We do not believe that other changes are needed to respond to these comments.

Final Sections 8.00F and 108.00F—How Do We Evaluate Burns?

Comment: One commenter stated that we should make clear that, when we evaluate burn victims under the musculoskeletal listings, it is the functional limitations that are being compared, not the underlying diagnostic criteria. For example, a burn may leave someone with the inability to move a joint, but the reason for the immobility will not be seen on x-ray. Therefore, it may not be clear that an individual could have an impairment that medically equals listing 1.02 or 101.02 because those listings include a requirement for appropriate medically acceptable imaging (such as an x-ray) showing joint space narrowing.

Response: We adopted the comment by adding new listings 8.08 and 108.08 for evaluating burns and by revising sections 8.00F and 108.00F. Final listings 8.08 and 108.08 now include burns that result in extensive skin lesions and that are not under continuing surgical management (as defined in 1.00M and 101.00M). With these final rules, it will no longer be necessary for our adjudicators to consider medical equivalence to a musculoskeletal listing when there is an extreme limitation resulting from extensive burn lesions.

We believe that this is a simpler solution to the problem raised by the commenter than clarifying how to use the musculoskeletal listings to show medical equivalence for individuals whose burns do not meet the requirements of listings 1.08 or 101.08. We will also continue to use listings 1.08 and 101.08 when there are burns that meet their criteria. We are also adding references to final section 8.00F and 108.00F in sections 1.00M and 101.00M to remind our adjudicators to consider these new provisions.

Final Sections 8.00G and 108.00G—How Do We Determine if Your Skin Disorder(s) Will Continue at a Disabling Level of Severity in Order To Meet the Duration Requirement?

Comment: Two commenters expressed concern about the requirement in proposed sections 8.00G and 108.00G, as well as other sections of the proposed rules, that skin lesions must persist for at least 3 months despite treatment. One commenter believed that our adjudicators would not properly consider conditions that go in and out of remission in periods shorter than 3 months, and said that such conditions might be disabling even if flareups are shorter than 3 months. The other commenter pointed out that in proposed sections 8.00B and 108.00B we indicated that we consider the frequency of flareups when we evaluate the severity of skin disorders. This commenter noted that we did not go on to provide any standards for considering flareups, especially when there are frequent flareups of shorter than 3 months despite treatment.

Response: We revised the rules to address these comments. Although the prior listings also contained a requirement that the lesions not respond to treatment, we agree that it is appropriate to provide guidance in the introductory text to the listings about how to consider frequent flareups. Therefore, in response to these comments, we are adding new sections 8.00C2 and 108.00C2, Frequency of flareups, in these final rules. The new sections explain that, if your skin lesions do not meet the requirements of one of these listings, your impairment may still medically equal one of the skin disorder listings. We explain that we will consider the frequency and seriousness of the flareups over time, especially if they result in extensive skin lesions, as described in final section 8.00C1, and even though there are intervening periods of remission. We must also consider how you function between flareups, and whether your impairment(s) has met or will meet the 12-month duration requirement.

We did not provide a specific number of episodes or specific rules regarding the seriousness or length of episodes because there are too many possible combinations of circumstances that could result in an impairment of listing-level severity. We will evaluate each case individually based on the evidence we have in the case record.

In addition, we added guidance in final sections 8.00H and 108.00H in response to these comments and the comment we summarize next. The new

text reminds our adjudicators that these listings are only examples of common skin disorders that we consider to be of listing-level severity. It also explains that we may still find you disabled under other listings, based on medical equivalence, or based on your residual functional capacity, age, education, and work experience (or, if you are a child claiming disability payments under SSI, based on functional equivalence). When we make these determinations, we will also consider the frequency of your flareups.

Comment: One commenter stated that, while it is true that most skin disorders are responsive to treatment, it is also true that not all claimants have access to health care. The commenter said that we should make it clear that claimants will not be penalized if they are unable to obtain state-of-the-art care.

Response: We adopted the comment. We revised sections 8.00H and 108.00H as explained in the preceding response.

As a point of clarification, it should be noted that you are not required to have ''state-of-the-art'' treatment to meet these listings, as the commenter assumed. As in all of our other listings that include requirements for persistence of findings despite treatment (see, for example, the cardiovascular body system listings in 4.00 and 104.00), we require only that you receive prescribed treatment in order to meet this requirement of the listings. We generally do not specify the kind or level of treatment. The treatment requirements in the listings are primarily to establish that the impairment is of a particular level of severity; that is, one that is so serious that it does not respond to medical treatment. You can still show that you are disabled in other ways if your impairment does not meet the requirements of a listing. Also, we use the listings only to find that people are disabled. We will never deny your claim or find that your disability has ended only because your impairment does not meet or medically equal the requirements of a listing.

Listings 8.03 and 108.03—Bullous Disease

Comment: One commenter asked us to rename this listing ''immunobullous disease.'' The commenter believed that this is a broader category and would allow for the inclusion of newly recognized diseases. The commenter also suggested that we add epidermolysis bullosa acquisita to the listing.

Response: We did not adopt the comment. We use the term ''bullous disease'' generically in our listings to include any disease that is characterized by bullae, including immunobullous diseases. The parenthetical examples of the kinds of impairments we intend to cover should make this clear because they include examples of immunobullous diseases. The fact that we list only some examples of bullous diseases should also make clear that we will evaluate epidermolysis bullosa acquisita under these listings and that they will include any newly discovered diseases that are characterized by bullae.

Listings 8.05 and 108.05—Dermatitis

Comment: One commenter suggested that we give psoriasis its own category instead of listing it with dermatitis, because psoriasis can affect the joints and other body systems in addition to the skin.

Response: We did not adopt the comment because we have other listings that address the effects of psoriasis in other body systems. See, for example, listings 14.09 and 114.09, which include psoriatic arthritis, as explained in 14.00B6 and 114.00E of the introductory text to those listings.

Comment: One commenter suggested that we address the role of temperature in listing 8.05 because extensive skin lesions from dermatitis can be, and often are, exacerbated by a lack of temperature control.

Response: We did not adopt the comment. We consider the role of temperature extremes when we evaluate your ability to do work-related activities. Therefore, we consider it when we determine whether you have a ''severe'' impairment and when we assess your residual functional capacity to determine whether you can do your past relevant work or any other work that exists in significant numbers in the national economy. See, generally, §§ 404.1520 and 416.920. We also consider the role of temperature extremes when we make findings about functional equivalence in children.

Comment: Another commenter asked us to add ''or other inflammation caused by rheumatic autoimmune conditions, such as Sjögren's syndrome'' to the examples of dermatitis in proposed listing 108.05.

Response: We did not adopt the specific suggestion, but we did add a reference to Sjögren's syndrome in final sections 8.00D3 and 108.00D3 in response to this comment. We refer specifically to Sjögren's syndrome in our instructions for applying listings 14.03 and 14.09 for adults and listing 114.09 for children in our immune system listings. See sections 14.00B2 and B6 and 114.00E of the introductory text to those body system listings. We can also use any other appropriate listing in the immune system. While Sjögren's syndrome can result in inflammation of the skin, we believe that it is most appropriate to consider it under the immune system listings.

The introductory text in the proposed rules included two paragraphs that explained how we evaluate individuals who have autoimmune disorders that can have effects on the skin. In the final rules, we combined the two paragraphs in final sections 8.00D3 and 108.00D3, and in response to these comments, we added Sjögren's syndrome to the list of examples of connective tissue disorders and other immune system disorders in those sections. We also included a reminder that we evaluate Sjögren's syndrome under listing 14.03, 14.09, 114.09, or any other appropriate immune system listing.

Listings 8.06 and 108.06—Hidradenitis Suppurativa

Comment: One commenter opposed our proposal to remove acne conglobata from this listing, stating that the debilitating state resulting from this disease can last for at least 3 months in some cases. The commenter believed that the most severely impaired acne conglobata patients should be considered eligible for disability benefits.

Response: We did not adopt the comment. To meet the statutory duration requirement, you must have a medically determinable impairment that has lasted or can be expected to last at a disabling level for a continuous period of at least 12 months. We require documentation of at least 3 months of persistent, extensive skin lesions in most of these listings because, for those listings that include this requirement, it is reasonable to assume that the disabling level of severity will continue for at least 12 months. Although we agree that some people with acne conglobata can be seriously limited for at least 3 months, we believe that it would be extremely rare for the condition to persist at a listing level of severity for a continuous period of at least 12 months. Therefore, we cannot presume that the duration requirement will be met after 3 months. We may still find individuals with the most serious cases of acne conglobata to be disabled using our other rules for determining disability based on medical equivalence or at later steps of the sequential evaluation processes for adults and children.

Comment: One commenter stated that the 3-month duration of treatment for hidradenitis suppurativa is too

restrictive and not realistic where antimicrobial treatment may be offered as part of a staged procedure that ends with surgical treatment.

Response: As we stated earlier, the 3-month duration of extensive skin lesions despite continuing treatment as prescribed (which includes both medical and surgical treatment) is only a criterion for meeting the listing. If your impairment does not meet this criterion, we may still find you disabled based on medical equivalence or at later steps of the sequential evaluation process.

Comment: One commenter noted that proposed section 108.00C1 used the phrase ''very serious limitations,'' instead of ''very serious limitation.'' He pointed out that, when read in the context of our definition of the term ''extreme'' in our functional equivalence regulation for children (§ 416.926a(e)(3)), the plural ''limitations'' might be misinterpreted as an even stricter standard than in the functional equivalence rule, which uses the singular form of the word.

Response: We adopted the comment. We now use the phrase ''a very serious limitation'' in both part A and part B of these final rules. Our intent in the NPRM was to describe an ''extreme'' limitation in the same way we use the term in the musculoskeletal listings for adults and children and in our functional equivalence rules. We also provide equivalent severity criteria in other listings, such as the neurological listings, that do not use the term ''extreme.''

Listings 8.07 and 108.07—Genetic Photosensitivity Disorders

Comment: We received comments from three commenters about the proposed listings for photosensitivity disorders, including xeroderma pigmentosum (XP). One commenter stated that proposed listings 8.07 and 108.07 did not make allowance for people with XP who may have not developed extensive skin lesions because they live extremely restricted lifestyles by totally avoiding sunlight. The commenter added that the listings should not require that one get sick in order to establish disability. Similarly, a second commenter described her personal experience with a child with XP. She explained that her son had had many surgeries for skin cancer and must stay in a specially protected home so he can avoid exposure to sunlight and any other ultraviolet light. She expressed concern that he would not meet proposed listing 108.07 because he did not have the extensive skin lesions required. The third commenter asked us to give more funding for research of XP, and to provide more assistance for the parents of children with XP and more education to the public about this disease.

Response: We adopted most of these comments. As we have already noted, we are adding listings 8.07A and 108.07A for adults and children with documented XP in response to these comments.

We are also adding new sections 8.00E and 108.00E to explain the criteria of the final listings and the documentation required to satisfy the listings. We also define the phrase ''inability to function outside of a highly protective environment,'' the severity criterion we use in final listings 8.07B and 108.07B. By adding these final rules, we will assist individuals with XP and other genetic photosensitivity disorders, and families who have children with these disorders, by providing them better access to disability benefits and, in many cases, access to health care through Medicare or Medicaid. The new rules also provide some information to the public about XP and how we consider it. However, we are unable to provide funding for research into XP or to provide training for the public about XP beyond what is required by our rules. These activities are not within our purview.

Other Comment

Comment: One commenter suggested that, instead of changing the body system name to ''Skin disorders,'' we change it to ''Skin, hair, nails, and mucous membranes'' because these denote the full range of body systems treated by dermatologists. The commenter noted that proposed listing 8.04 included a reference to the mucous membranes.

Response: We did not adopt the comment. The headings of our body systems explain the kinds of disorders we list within the body systems, not the range of conditions treated by particular medical specialties. Since these listings include primarily disorders of the skin, we are not changing the heading. Although we refer to mucous membranes in final listings 8.04 and 108.04, Chronic infections of the skin or mucous membranes, it is only to recognize that infections of the skin often involve the mucous membranes.

Regulatory Procedures

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 do 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

The Paperwork Reduction Act (PRA) of 1995 says that no persons are required to respond to a collection of information unless it displays a valid OMB control number. In accordance with the PRA, SSA is providing notice that OMB has approved the information collection requirements contained in sections 8.00C, 8.00D, 108.00B, 108.00C and 108.00D of these final rules. The OMB Control Number for this collection is 0960–0642 expiring 12/31/2004.

(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 in 20 CFR Part 404

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

Dated: March 12, 2004.

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–)

Subpart P—Determining Disability and Blindness

■ 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. Appendix 1 to subpart P of part 404 is amended as follows:
■ a. Item 9 of the introductory text before part A of appendix 1 is amended by revising the body system name, revising the expiration date for section 8.00, and adding section 108.00 and its expiration date.
■ b. The list of sections for part A of appendix 1 is amended by revising the body system name for section 8.00.
■ c. Section 1.00M of part A of appendix 1 is amended by adding a new last sentence to the paragraph.
■ d. Section 8.00 of part A of appendix 1 is revised.
■ e. The list of sections for part B of appendix 1 is amended by revising section 108.00 to read ''108.00 Skin Disorders''.
■ f. Section 101.00M of part B of appendix 1 is amended by adding a new last sentence to the paragraph.
■ g. Section 108.00 of part B of appendix 1 is added.

The new and revised text is set forth as follows:

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

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9. Skin Disorders (8.00 and 108.00): July 9, 2012.

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Part A

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8.00 Skin Disorders

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1.00 Musculoskeletal System

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M. * * * When burns are not under continuing surgical management, see 8.00F.

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8.00 Skin Disorders

A. *What skin disorders do we evaluate with these listings?* We use these listings to evaluate skin disorders that may result from hereditary, congenital, or acquired pathological processes. The kinds of impairments covered by these listings are: Ichthyosis, bullous diseases, chronic infections of the skin or mucous membranes, dermatitis, hidradenitis suppurativa, genetic photosensitivity disorders, and burns.

B. *What documentation do we need?* When we evaluate the existence and severity of your skin disorder, we generally need information about the onset, duration, frequency of flareups, and prognosis of your skin disorder; the location, size, and appearance of lesions; and, when applicable, history of exposure to toxins, allergens, or irritants, familial incidence, seasonal variation, stress factors, and your ability to function outside of a highly protective environment. To confirm the diagnosis, we may need laboratory findings (for example, results of a biopsy obtained independently of Social Security disability evaluation or blood tests) or evidence from other medically acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

C. *How do we assess the severity of your skin disorder(s)?* We generally base our assessment of severity on the extent of your skin lesions, the frequency of flareups of your skin lesions, how your symptoms (including pain) limit you, the extent of your treatment, and how your treatment affects you.

1. *Extensive skin lesions.* Extensive skin lesions are those that involve multiple body sites or critical body areas, and result in a very serious limitation. Examples of extensive skin lesions that result in a very serious limitation include but are not limited to:

a. Skin lesions that interfere with the motion of your joints and that very seriously limit your use of more than one extremity; that is, two upper extremities, two lower extremities, or one upper and one lower extremity.

b. Skin lesions on the palms of both hands that very seriously limit your ability to do fine and gross motor movements.

c. Skin lesions on the soles of both feet, the perineum, or both inguinal areas that very seriously limit your ability to ambulate.

2. *Frequency of flareups.* If you have skin lesions, but they do not meet the requirements of any of the listings in this body system, you may still have an impairment that prevents you from doing any gainful activity when we consider your condition over time, especially if your flareups result in extensive skin lesions, as defined in C1 of this section. Therefore, if you have frequent flareups, we may find that your impairment(s) is medically equal to one of these listings even though you have some periods during which your condition is in remission. We will consider how frequent and serious your flareups are, how quickly they resolve, and how you function between flareups to determine whether you have been unable to do any gainful activity for a continuous period of at least 12 months or can be expected to be unable to do any gainful activity for a continuous period of at least 12 months. We will also consider the frequency of your flareups when we determine whether you have a severe impairment and when we need to assess your residual functional capacity.

3. *Symptoms (including pain).* Symptoms (including pain) may be important factors contributing to the severity of your skin disorder(s). We assess the impact of symptoms as explained in §§ 404.1528, 404.1529, 416.928, and 416.929 of this chapter.

4. *Treatment.* We assess the effects of medication, therapy, surgery, and any other form of treatment you receive when we determine the severity and duration of your impairment(s). Skin disorders frequently respond to treatment; however, response to treatment can vary widely, with some impairments becoming resistant to treatment. Some treatments can have side effects that can in themselves result in limitations.

a. We assess the effects of continuing treatment as prescribed by determining if there is improvement in the symptoms, signs, and laboratory findings of your disorder, and if you experience side effects that result in functional limitations. To assess the effects of your treatment, we may need information about:

i. The treatment you have been prescribed (for example, the type, dosage, method, and frequency of administration of medication or therapy);

ii. Your response to the treatment;

iii. Any adverse effects of the treatment; and

iv. The expected duration of the treatment.

b. Because treatment itself or the effects of treatment may be temporary, in most cases sufficient time must elapse to allow us to evaluate the impact and expected duration of treatment and its side effects. Except under 8.07 and 8.08, you must follow continuing treatment as prescribed for at least 3 months before your impairment can be determined to meet the requirements of a skin disorder listing. (See 8.00H if you are not undergoing treatment or did not have treatment for 3 months.) We consider your specific response to treatment when we evaluate the overall severity of your impairment.

D. *How do we assess impairments that may affect the skin and other body systems?* When your impairment affects your skin and has effects in other body systems, we first evaluate the predominant feature of your impairment under the appropriate body system. Examples include, but are not limited to the following.

1. *Tuberous sclerosis* primarily affects the brain. The predominant features are seizures, which we evaluate under the neurological listings in 11.00, and developmental delays or other mental disorders, which we evaluate under the mental disorders listings in 12.00.

2. *Malignant tumors of the skin* (for example, malignant melanomas) are cancers, or neoplastic diseases, which we evaluate under the listings in 13.00.

3. *Connective tissue disorders and other immune system disorders* (for example, systemic lupus erythematosus, scleroderma, human immunodeficiency virus (HIV) infection, and Sjögren's syndrome) often involve more than one body system. We first evaluate these disorders under the immune system listings in 14.00. We evaluate lupus erythematosus under 14.02, scleroderma under 14.04, symptomatic HIV infection under 14.08, and Sjögren's syndrome under 14.03, 14.09, or any other appropriate listing in section 14.00.

4. *Disfigurement or deformity* resulting from skin lesions may result in loss of sight, hearing, speech, and the ability to chew (mastication). We evaluate these impairments and their effects under the special senses and speech listings in 2.00 and the digestive system listings in 5.00. Facial disfigurement or other physical deformities may also have effects we evaluate under the mental disorders listings in 12.00, such as when they affect mood or social functioning.

E. *How do we evaluate genetic photosensitivity disorders?*

1. *Xeroderma pigmentosum (XP).* When you have XP, your impairment meets the

requirements of 8.07A if you have clinical and laboratory findings showing that you have the disorder. (See 8.00E3.) People who have XP have a lifelong hypersensitivity to all forms of ultraviolet light and generally lead extremely restricted lives in highly protective environments in order to prevent skin cancers from developing. Some people with XP also experience problems with their eyes, neurological problems, mental disorders, and problems in other body systems.

2. *Other genetic photosensitivity disorders.* Other genetic photosensitivity disorders may vary in their effects on different people, and may not result in an inability to engage in any gainful activity for a continuous period of at least 12 months. Therefore, if you have a genetic photosensitivity disorder other than XP (established by clinical and laboratory findings as described in 8.00E3), you must show that you have either extensive skin lesions or an inability to function outside of a highly protective environment to meet the requirements of 8.07B. You must also show that your impairment meets the duration requirement. By *inability to function outside of a highly protective environment* we mean that you must avoid exposure to ultraviolet light (including sunlight passing through windows and light from unshielded fluorescent bulbs), wear protective clothing and eyeglasses, and use opaque broad-spectrum sunscreens in order to avoid skin cancer or other serious effects. Some genetic photosensitivity disorders can have very serious effects in other body systems, especially special senses and speech (2.00), neurological (11.00), mental (12.00), and neoplastic (13.00). We will evaluate the predominant feature of your impairment under the appropriate body system, as explained in 8.00D.

3. *Clinical and laboratory findings.* We need evidence confirming the diagnosis of your XP or other genetic photosensitivity disorder. The evidence must include a clinical description of abnormal physical findings associated with the condition. There must also be definitive genetic laboratory studies documenting appropriate chromosomal damage, abnormal DNA repair, or other DNA or genetic abnormality specific to your type of photosensitivity disorder. However, we do not need a copy of the actual laboratory report if we have medical evidence that is persuasive that a positive diagnosis has been confirmed by laboratory testing.

F. *How do we evaluate burns?* Electrical, chemical, or thermal burns frequently affect other body systems; for example, musculoskeletal, special senses and speech, respiratory, cardiovascular, renal, neurological, or mental. Consequently, we evaluate burns the way we evaluate other disorders that can affect the skin and other body systems, using the listing for the predominant feature of your impairment. For example, if your soft tissue injuries are under continuing surgical management (as defined in 1.00M), we will evaluate your impairment under 1.08. However, if your burns do not meet the requirements of 1.08 and you have extensive skin lesions that result in a very serious limitation (as defined in 8.00C1) that has lasted or can be expected to last for a continuous period of at least 12 months, we will evaluate them under 8.08.

G. *How do we determine if your skin disorder(s) will continue at a disabling level of severity in order to meet the duration requirement?* For all of these skin disorder listings except 8.07 and 8.08, we will find that your impairment meets the duration requirement if your skin disorder results in extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed. By *persist,* we mean that the longitudinal clinical record shows that, with few exceptions, your lesions have been at the level of severity specified in the listing. For 8.07A, we will presume that you meet the duration requirement. For 8.07B and 8.08, we will consider all of the relevant medical and other information in your case record to determine whether your skin disorder meets the duration requirement.

H. *How do we assess your skin disorder(s) if your impairment does not meet the requirements of one of these listings?*

1. These listings are only examples of common skin disorders that we consider severe enough to prevent you from engaging in any gainful activity. For most of these listings, if you do not have continuing treatment as prescribed, if your treatment has not lasted for at least 3 months, or if you do not have extensive skin lesions that have persisted for at least 3 months, your impairment cannot meet the requirements of these skin disorder listings. (This provision does not apply to 8.07 and 8.08.) However, we may still find that you are disabled because your impairment(s) meets the requirements of a listing in another body system or medically equals the severity of a listing. (See §§ 404.1526 and 416.926 of this chapter.) We may also find you disabled at the last step of the sequential evaluation process.

2. If you have not received ongoing treatment or do not have an ongoing relationship with the medical community despite the existence of a severe impairment(s), or if your skin lesions have not persisted for at least 3 months but you are undergoing continuing treatment as prescribed, you may still have an impairment(s) that meets a listing in another body system or that medically equals a listing. If you do not have an impairment(s) that meets or medically equals a listing, we will assess your residual functional capacity and proceed to the fourth and, if necessary, the fifth step of the sequential evaluation process in §§ 404.1520 and 416.920 of this chapter. When we decide whether you continue to be disabled, we use the rules in §§ 404.1594 and 416.994 of this chapter.

8.01 Category of Impairments, Skin Disorders

8.02 *Ichthyosis,* with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

8.03 *Bullous disease* (for example, pemphigus, erythema multiforme bullosum, epidermolysis bullosa, bullous pemphigoid, dermatitis herpetiformis), with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

8.04 *Chronic infections of the skin or mucous membranes,* with extensive fungating or extensive ulcerating skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

8.05 *Dermatitis* (for example, psoriasis, dyshidrosis, atopic dermatitis, exfoliative dermatitis, allergic contact dermatitis), with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

8.06 *Hidradenitis suppurativa,* with extensive skin lesions involving both axillae, both inguinal areas or the perineum that persist for at least 3 months despite continuing treatment as prescribed.

8.07 *Genetic photosensitivity disorders,* established by clinical and laboratory findings as described in 8.00E.

A. Xeroderma pigmentosum. Consider the individual disabled from birth.

B. Other genetic photosensitivity disorders, with:

1. Extensive skin lesions that have lasted or can be expected to last for a continuous period of at least 12 months, or

2. Inability to function outside of a highly protective environment for a continuous period of at least 12 months (see 8.00E2).

8.08 *Burns,* with extensive skin lesions that have lasted or can be expected to last for a continuous period of at least 12 months (see 8.00F).

* * * * *

Part B

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108.00 Skin Disorders

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101.00 Musculoskeletal System

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M. * * * When burns are not under continuing surgical management, see 108.00F.

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108.00 Skin Disorders

A. *What skin disorders do we evaluate with these listings?* We use these listings to evaluate skin disorders that may result from hereditary, congenital, or acquired pathological processes. The kinds of impairments covered by these listings are: Ichthyosis, bullous diseases, chronic infections of the skin or mucous membranes, dermatitis, hidradenitis suppurativa, genetic photosensitivity disorders, and burns.

B. *What documentation do we need?* When we evaluate the existence and severity of your skin disorder, we generally need information about the onset, duration, frequency of flareups, and prognosis of your skin disorder; the location, size, and appearance of lesions; and, when applicable, history of exposure to toxins, allergens, or irritants, familial incidence, seasonal variation, stress factors, and your ability to function outside of a highly protective environment. To confirm the diagnosis, we may need laboratory findings (for example, results of a biopsy obtained independently of Social Security disability evaluation or blood tests) or evidence from other medically acceptable methods consistent with the

prevailing state of medical knowledge and clinical practice.

C. *How do we assess the severity of your skin disorders(s)?* We generally base our assessment of severity on the extent of your skin lesions, the frequency of flareups of your skin lesions, how your symptoms (including pain) limit you, the extent of your treatment, and how your treatment affects you.

1. *Extensive skin lesions.* Extensive skin lesions are those that involve multiple body sites or critical body areas, and result in a very serious limitation. Examples of extensive skin lesions that result in a very serious limitation include but are not limited to:

a. Skin lesions that interfere with the motion of your joints and that very seriously limit your use of more than one extremity; that is, two upper extremities, two lower extremities, or one upper and one lower extremity.

b. Skin lesions on the palms of both hands that very seriously limit your ability to do fine and gross motor movements.

c. Skin lesions on the soles of both feet, the perineum, or both inguinal areas that very seriously limit your ability to ambulate.

2. *Frequency of flareups.* If you have skin lesions, but they do not meet the requirements of any of the listings in this body system, you may still have an impairment that results in marked and severe functional limitations when we consider your condition over time, especially if your flareups result in extensive skin lesions, as defined in C1 of this section. Therefore, if you have frequent flareups, we may find that your impairment(s) is medically equal to one of these listings even though you have some periods during which your condition is in remission. We will consider how frequent and serious your flareups are, how quickly they resolve, and how you function between flareups to determine whether you have marked and severe functional limitations that have lasted for a continuous period of at least 12 months or that can be expected to last for a continuous period of at least 12 months. We will also consider the frequency of your flareups when we determine whether you have a severe impairment and when we need to assess functional equivalence.

3. *Symptoms (including pain).* Symptoms (including pain) may be important factors contributing to the severity of your skin disorder(s). We assess the impact of symptoms as explained in §§ 404.1528, 404.1529, 416.928, and 416.929 of this chapter.

4. *Treatment.* We assess the effects of medication, therapy, surgery, and any other form of treatment you receive when we determine the severity and duration of your impairment(s). Skin disorders frequently respond to treatment; however, response to treatment can vary widely, with some impairments becoming resistant to treatment. Some treatments can have side effects that can in themselves result in limitations.

a. We assess the effects of continuing treatment as prescribed by determining if there is improvement in the symptoms, signs, and laboratory findings of your disorder, and if you experience side effects that result in functional limitations. To assess the effects of your treatment, we may need information about:

i. The treatment you have been prescribed (for example, the type, dosage, method and frequency of administration of medication or therapy);

ii. Your response to the treatment;

iii. Any adverse effects of the treatment; and

iv. The expected duration of the treatment.

b. Because treatment itself or the effects of treatment may be temporary, in most cases sufficient time must elapse to allow us to evaluate the impact and expected duration of treatment and its side effects. Except under 108.07 and 108.08, you must follow continuing treatment as prescribed for at least 3 months before your impairment can be determined to meet the requirements of a skin disorder listing. (See 108.00H if you are not undergoing treatment or did not have treatment for 3 months.) We consider your specific response to treatment when we evaluate the overall severity of your impairment.

D. *How do we assess impairments that may affect the skin and other body systems?* When your impairment affects your skin and has effects in other body systems, we first evaluate the predominant feature of your impairment under the appropriate body system. Examples include, but are not limited to the following.

1. *Tuberous sclerosis* primarily affects the brain. The predominant features are seizures, which we evaluate under the neurological listings in 111.00, and developmental delays or other mental disorders, which we evaluate under the mental disorders listings in 112.00.

2. *Malignant tumors of the skin* (for example, malignant melanoma) are cancers, or neoplastic diseases, which we evaluate under the listings in 113.00.

3. *Connective tissue disorders and other immune system disorders* (for example, systemic lupus erythematosus, scleroderma, human immunodeficiency virus (HIV) infection, and Sjögren's syndrome) often involve more than one body system. We first evaluate these disorders under the immune system listings in 114.00. We evaluate lupus erythematosus under 114.02, scleroderma under 114.04, symptomatic HIV infection under 114.08, and Sjögren's syndrome under 114.03, 114.09, or any other appropriate listing in section 114.00.

4. *Disfigurement or deformity* resulting from skin lesions may result in loss of sight, hearing, speech, and the ability to chew (mastication). We evaluate these impairments and their effects under the special senses and speech listings in 102.00 and the digestive system listings in 105.00. Facial disfigurement or other physical deformities may also have effects we evaluate under the mental disorders listings in 112.00, such as when they affect mood or social functioning.

5. We evaluate *erythropoietic porphyrias* under the hemic and lymphatic listings in 107.00.

6. We evaluate *hemangiomas associated with thrombocytopenia and hemorrhage* (for example, Kasabach-Merritt syndrome) involving coagulation defects, under the hemic and lymphatic listings in 107.00. But, when hemangiomas impinge on vital structures or interfere with function, we evaluate their primary effects under the appropriate body system.

E. *How do we evaluate genetic photosensitivity disorders?*

1. *Xeroderma pigmentosum (XP).* When you have XP, your impairment meets the requirements of 108.07A if you have clinical and laboratory findings showing that you have the disorder. (See 108.00E3.) People who have XP have a lifelong hypersensitivity to all forms of ultraviolet light and generally lead extremely restricted lives in highly protective environments in order to prevent skin cancers from developing. Some people with XP also experience problems with their eyes, neurological problems, mental disorders, and problems in other body systems.

2. *Other genetic photosensitivity disorders.* Other genetic photosensitivity disorders may vary in their effects on different people, and may not result in marked and severe functional limitations for a continuous period of at least 12 months. Therefore, if you have a genetic photosensitivity disorder other than XP (established by clinical and laboratory findings as described in 108.00E3), you must show that you have either extensive skin lesions or an inability to function outside of a highly protective environment to meet the requirements of 108.07B. You must also show that your impairment meets the duration requirement. By *inability to function outside of a highly protective environment* we mean that you must avoid exposure to ultraviolet light (including sunlight passing through windows and light from unshielded fluorescent bulbs), wear protective clothing and eyeglasses, and use opaque broad-spectrum sunscreens in order to avoid skin cancer or other serious effects. Some genetic photosensitivity disorders can have very serious effects in other body systems, especially special senses and speech (102.00), neurological (111.00), mental (112.00), and neoplastic (113.00). We will evaluate the predominant feature of your impairment under the appropriate body system, as explained in 108.00D.

3. *Clinical and laboratory findings.* We need evidence confirming the diagnosis of your XP or other genetic photosensitivity disorder. The evidence must include a clinical description of abnormal physical findings associated with the condition. There must also be definitive genetic laboratory studies documenting appropriate chromosomal damage, abnormal DNA repair, or other DNA or genetic abnormality specific to your type of photosensitivity disorder. However, we do not need a copy of the actual laboratory report if we have medical evidence that is persuasive that a positive diagnosis has been confirmed by laboratory testing.

F. *How do we evaluate burns?* Electrical, chemical, or thermal burns frequently affect other body systems; for example, musculoskeletal, special senses and speech, respiratory, cardiovascular, renal, neurological, or mental. Consequently, we evaluate burns the way we evaluate other disorders that can affect the skin and other body systems, using the listing for the predominant feature of your impairment. For

example, if your soft tissue injuries are under continuing surgical management (as defined in 101.00M), we will evaluate your impairment under 101.08. However, if your burns do not meet the requirements of 101.08 and you have extensive skin lesions that result in a very serious limitation (as defined in 108.00C1) that has lasted or can be expected to last for a continuous period of at least 12 months, we will evaluate them under 108.08.

G. *How do we determine if your skin disorder(s) will continue at a disabling level of severity in order to meet the duration requirement?* For all of these skin disorder listings except 108.07 and 108.08, we will find that your impairment meets the duration requirement if your skin disorder results in extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed. By *persist*, we mean that the longitudinal clinical record shows that, with few exceptions, your lesions have been at the level of severity specified in the listing. For 108.07A, we will presume that you meet the duration requirement. For 108.07B and 108.08, we will consider all of the relevant medical and other information in your case record to determine whether your skin disorder meets the duration requirement.

H. *How do we assess your skin disorder(s) if your impairment does not meet the requirements of one of these listings?*

1. These listings are only examples of common skin disorders that we consider severe enough to result in marked and severe functional limitations. For most of these listings, if you do not have continuing treatment as prescribed, if your treatment has not lasted for at least 3 months, or if you do not have extensive skin lesions that have persisted for at least 3 months, your impairment cannot meet the requirements of these skin disorder listings. (This provision does not apply to 108.07 and 108.08.) However, we may still find that you are disabled because your impairment(s) meets the requirements of a listing in another body system, medically equals (see §§ 404.1526 and 416.926 of this chapter) the severity of a listing, or functionally equals the severity of the listings.

2. If you have not received ongoing treatment or do not have an ongoing relationship with the medical community despite the existence of a severe impairment(s), or if your skin lesions have not persisted for at least 3 months but you are undergoing continuing treatment as prescribed, you may still have an impairment(s) that meets a listing in another body system or that medically equals a listing. If you do not have an impairment(s) that meets or medically equals a listing, we will consider whether your impairment(s) functionally equals the listings. (See § 416.924 of this chapter.) When we decide whether you continue to be disabled, we use the rules in § 416.994a of this chapter.

108.01 Category of Impairments, Skin Disorders

108.02 *Ichthyosis*, with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

108.03 *Bullous disease* (for example, pemphigus, erythema multiforme bullosum, epidermolysis bullosa, bullous pemphigoid, dermatitis herpetiformis), with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

108.04 *Chronic infections of the skin or mucous membranes*, with extensive fungating or extensive ulcerating skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

108.05 *Dermatitis* (for example, psoriasis, dyshidrosis, atopic dermatitis, exfoliative dermatitis, allergic contact dermatitis), with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

108.06 *Hidradenitis suppurativa*, with extensive skin lesions involving both axillae, both inguinal areas, or the perineum that persist for at least 3 months despite continuing treatment as prescribed.

108.07 *Genetic photosensitivity disorders*, established by clinical and laboratory findings as described in 108.00E.

A. Xeroderma pigmentosum. Consider the individual disabled from birth.

B. Other genetic photosensitivity disorders, with:

1. Extensive skin lesions that have lasted or can be expected to last for a continuous period of at least 12 months, or

2. Inability to function outside of a highly protective environment for a continuous period of at least 12 months (see 108.00E2).

108.08 *Burns*, with extensive skin lesions that have lasted or can be expected to last for a continuous period of at least 12 months. (See 108.00F).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Clindamycin Capsules and Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of two supplemental abbreviated new animal drug applications (ANADAs) filed by Phoenix Scientific, Inc. One supplemental ANADA provides for an expanded dose range and revised indications wording for the oral use of clindamycin hydrochloride capsules in dogs for the treatment of certain bacterial diseases. The other supplemental ANADA provides for use of a 300-milligram capsule size.

DATES: This rule is effective June 9, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed two supplements to ANADA 200–298 for Clindamycin Hydrochloride Capsules. One supplemental ANADA provides for an expanded dose range and revised indications wording for the oral use of clindamycin hydrochloride capsules in dogs for the treatment of certain bacterial diseases. The other supplemental ANADA provides for use of a 300-milligram capsule size. The supplemental applications are approved as of April 21, 2004, and the regulations are amended in 21 CFR 520.446 to reflect their approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required for either.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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