

establishing the new port of entry as proposed and Tri-Cities Regional Airport will lose its status as a user-fee airport. The change of status for Tri-Cities Regional Airport from a user-fee airport to inclusion within the boundaries of a port of entry will subject the airport to the passenger processing fee provided for at 19 U.S.C. 58c(a)(5)(B).

Description of the New Port of Entry Limits

The geographical limits of the Tri-Cities, TNNA, port of entry are as follows:

The contiguous outer boundaries of Sullivan County, Tennessee; Washington County, Tennessee; and Washington County, Virginia.

Authority

This change is made under the authority of 5 U.S.C. 301 and 19 U.S.C. 2, 66, and 1624, and the Homeland Security Act of 2002, Public Law 107–296 (November 25, 2002).

The Regulatory Flexibility Act and Executive Order 12866

With DHS approval, CBP establishes, expands and consolidates CBP ports of entry throughout the United States to accommodate the volume of CBP-related activity in various parts of the country. This final rule is not a significant regulatory action within the meaning of Executive Order 12866. This action also will not have a significant economic impact on a substantial number of small entities. Accordingly, DHS certifies that this document is not subject to the additional requirements of the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Signing Authority

The signing authority for this document falls under 19 CFR 0.2(a) because the establishment of a new port of entry and the termination of the user-fee status of an airport are not within the bounds of those regulations for which the Secretary of the Treasury has retained sole authority. Accordingly, this final rule may be signed by the Secretary of Homeland Security (or his or her delegate).

List of Subjects

19 CFR Part 101

Customs duties and inspection, Customs ports of entry, Exports, Imports, Organization and functions (Government agencies).

19 CFR Part 122

Customs duties and inspection, Airports, Imports, Organization and functions (Government agencies).

Amendments to CBP Regulations

■ For the reasons set forth above, part 101, CBP Regulations (19 CFR part 101), and part 122, CBP Regulations (19 CFR part 122), are amended as set forth below.

PART 101—GENERAL PROVISIONS

■ 1. The general authority citation for part 101 and the specific authority citation for § 101.3 continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 2, 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1623, 1624, 1646a.

Sections 101.3 and 101.4 also issued under 19 U.S.C. 1 and 58b;

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§ 101.3 [Amended]

■ 2. The list of ports in § 101.3(b)(1) is amended by adding, in alphabetical order under the state of Tennessee, “Tri-Cities, TN/VA” in the “Ports of entry” column and “CBP Dec. 06–14” in the “Limits of Port” column.

PART 122—AIR COMMERCE REGULATIONS

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

Authority: 5 U.S.C. 301; 19 U.S.C. 58b, 66, 1431, 1433, 1436, 1448, 1459, 1590, 1594, 1623, 1624, 1644, 1644a, 2071 note.

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§ 122.15 [Amended]

■ 2. The list of user fee airports at 19 CFR 122.15(b) is amended by removing “Blountville, Tennessee” from the “Location” column and, on the same line, “Tri-City Regional Airport” from the “Name” column.

Dated: May 9, 2006.

Michael Chertoff,
Secretary.

[FR Doc. 06–4535 Filed 5–15–06; 8:45 am]

BILLING CODE 9111–14–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 416

RIN 0960–AG00

Rules for Helping Blind and Disabled Individuals Achieve Self-Support

AGENCY: Social Security Administration.

ACTION: Final rules.

SUMMARY: We are amending our regulations to implement section 203 of the Social Security Independence and Program Improvements Act of 1994. Section 203 of this law amended section 1633 of the Social Security Act to require us to establish by regulations criteria for time limits and other criteria related to plans to achieve self-support (PASS). The law requires that we establish criteria for a PASS and that when we set time limits for your PASS, we take into account the length of time that you need to achieve your employment goal, within a reasonable period.

A PASS allows some persons who receive or are eligible for Supplemental Security Income (SSI) disability benefits to set aside part of their income and/or resources to meet an employment goal. The income and/or resources you set aside under a PASS will not be counted in determining the amount of your SSI payment or eligibility.

DATES: These final rules are effective on June 15, 2006.

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>.

FOR FURTHER INFORMATION CONTACT:

Mary Hoover, Policy Analyst, Office of Program Development and Research, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401. Call 410–965–5651 or TTY 1–800–325–0778 for information about these rules. For information on eligibility or filing for benefits, call our national toll-free number 1–800–772–1213 or TTY 1–800–325–0778. You may also contact Social Security Online at <http://www.socialsecurity.gov/>.

SUPPLEMENTARY INFORMATION:

What Is the Purpose of These Final Rules?

In these final rules, we are amending our regulations to implement section 203 of the Social Security Independence and Program Improvements Act of 1994 (Pub. L. 103–296). This law amended section 1633 of the Social Security Act to provide that, as of January 1, 1995, in establishing time limits and other criteria related to a PASS, we take into account the length of time that you will need to achieve your employment goal, within a reasonable period, and other factors as determined by the Commissioner to be appropriate. This requirement for a more individualized time limit changed the time limit requirements for PASS, which had provided for an initial period of not

more than 18 months, an extension of up to an additional 18 months, and a maximum of 48 months. We are revising our rules to take into account your individual needs and your employment goal in determining what a reasonable length of time is to achieve your employment goal. These revisions add language to some of our rules describing the information that must be contained in a PASS. They clarify requirements currently in our PASS rules and operating procedures. These revisions do not reflect a change in policy because after the enactment of Public Law 103–296, we updated our operating manual to reflect the need for a more individualized assessment of a PASS time limit.

What Is a Plan to Achieve Self-Support (PASS)?

A PASS allows persons who are blind or disabled and who receive, are eligible for, or are applying for SSI, to set aside income and/or resources for expenses needed in meeting an employment goal. We will not count the income and/or resources set aside under a PASS in determining your eligibility for and receipt of SSI. If you receive title II disability benefits, you may also use a PASS to meet an employment goal if you:

- Would meet all other income and resource eligibility requirements for SSI if some or all of your title II benefit was excluded;
- Apply for SSI; and
- Develop an approved PASS that sets aside some or all of your title II benefit towards meeting an employment goal.

The purpose of a PASS is to help persons who are blind or disabled become self-supporting. A PASS must meet specific requirements that are set out in our regulations at 20 CFR 416.1180 through 416.1182 and in chapter SI 00870 of our Program Operations Manual at: <http://policy.ssa.gov/poms.nsf/partlist?OpenView>. It must be individualized with an employment goal that is feasible and with a plan to reach that employment goal that is viable for you. It must be in writing, contain reasonable start and ending dates for meeting your employment goal, and establish target dates for milestones, i.e., intermediate steps towards attainment of your goal. It must be approved by us, and we will review your progress under the plan at least annually.

What Revisions Are We Making and Why?

As of January 1, 1995, section 1633(d) of the Act has required that, in establishing time limits and other criteria for a PASS, we consider the reasonable amount of time that you need to meet your employment goal and other factors that we determine are appropriate.

We are revising our rules to eliminate the current monthly time limits and to add rules that will take into account your individual needs and your employment goal in determining what a reasonable length of time is for you to achieve that goal. These revisions describe the requirements for and contents of a PASS to clarify requirements currently in our PASS rules and operating procedures. These revisions clarify that a PASS must have a feasible employment goal, a viable plan to reach that goal, and have reasonable beginning and ending dates, including target dates for milestones toward completion of the goal. The revisions state that we will review progress under a plan at least annually. We will help you establish a reasonable ending date for your PASS. We may adjust or extend the ending date of your PASS based on progress towards your goal and earnings level reached. We will review your PASS progress at least annually to determine if you continue to follow the provisions of your PASS.

Specific Changes

The following is an explanation of the specific changes we are making. We are revising § 416.1180 by adding that we will exclude income used to meet expenses that are reasonable and necessary to fulfill an approved PASS and to make a minor change in terminology. In addition, we are revising § 416.1225 to clarify that we will not count resources that are used for expenses that are reasonable and necessary to fulfill a PASS. Requiring that the expenses be reasonable and necessary to fulfill a PASS is not a change in policy. It is contained in our operating procedures.

We are revising § 416.1181 to list the requirements of a PASS that sets aside income to meet an employment goal and § 416.1226 to list the requirements of a PASS that sets aside resources to meet an employment goal. A PASS must be individualized, be in writing, specify an employment goal that is feasible, include a plan to reach the goal that is viable for you, and contain a start date, ending date and target milestone dates for meeting your employment goal. You must propose a reasonable ending date

to your PASS. If necessary, we will help you establish an ending date, which may be different than the ending date that you propose. Before you begin your PASS, we must approve it. After your PASS is approved and you begin following your PASS, we may adjust or extend the PASS ending date based on progress towards your goal and earnings level reached. We will review your PASS progress at least annually to determine if you continue to follow the provisions of your PASS.

A PASS that sets aside income or resources must show anticipated expenses and explain how they are necessary for the employment goal. It must show anticipated income (or resources you have and will receive) and explain how the income or resources will be used to meet expenses towards the employment goal. It must show how the money or resources set aside under a PASS will be kept separate from other funds or resources. It must show how living expenses will be met while the PASS is in effect. If the employment goal is self-employment, it must include a plan that defines the business, provides a marketing strategy, details financial data, outlines the operational procedures, and describes the management plan.

Public Comments

On July 11, 2005, we published proposed rules in the **Federal Register** (70 FR 39689) and provided a 60-day comment period. We received comments from five individuals and four advocacy organizations. All of the commenters support the implementation of these rules, although some requested further elaboration of specific terms used in the rules. Some of the commenters made recommendations that were outside the scope of these rules. Because some of the comments received were quite detailed, we have condensed, summarized or paraphrased them in the discussion below. We have tried to present all views adequately and carefully address all of the issues raised by the commenters that are within the scope of these rules.

Comment: One commenter asked that we provide a better explanation of what we mean by a feasible employment goal and a viable plan in §§ 416.1181(a)(4) and 416.1226(a)(4).

Response: We are adopting this commenter's recommendation. We have expanded §§ 416.1181(a)(4) and 416.1226(a)(4) to define what we mean by a feasible employment goal. A feasible employment goal is one that you have a reasonable likelihood of achieving. Additionally, we have added

a new § 416.1181(a)(5) and § 416.1226(a)(5) to explain what we mean by a viable plan. A plan is viable if it sets forth attainable steps to reach your goal and if it is financially sustainable, that is, the plan will leave you with enough money to meet living expenses while you set aside income or resources to meet your goal. We have renumbered the remaining paragraphs.

Comment: Two commenters recommended that we provide an example of what we mean by a reasonable ending date for a PASS and that we delineate what we consider a reasonable period for completion of a PASS.

Response: The legislation requires that we establish time limits that take your needs into account. We will assess your current needs, education, work experience, income and resources, and compare that to your ultimate employment goal and plan for reaching that goal, to determine an appropriate ending date. This is a highly individualized assessment. We do not believe an example would be useful, given the wide variety of individual factors used to determine an appropriate ending date. For this reason, we are not adopting this commenter's recommendation.

Comment: Two commenters asked how much of a reduction is "substantial" when we say that the goal should generate sufficient earnings to substantially reduce or eliminate your dependence on SSI or eliminate your need for title II benefits. These commenters also recommended that we provide an example.

Response: The PASS employment goal should generate sufficient earnings to substantially reduce or eliminate your dependence on SSI or eliminate your need for title II disability benefits. The nature of a PASS is highly individualized and the specific financial and personal circumstances for each individual can vary widely; therefore, we have chosen not to place a numerical value on the meaning of "substantially reduce your dependence on SSI" that would apply in every situation. However, we agree that examples may help clarify what we mean by "substantial." Therefore, we are adopting this recommendation with modifications.

Regulatory Procedures

Executive Order (E.O.) 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 E.O. 12866, as amended by

E.O. 13256. Thus, they were subject to OMB review.

Regulatory Flexibility Act

We certify that these regulations would not have a significant economic impact on a substantial number of small entities because they affect only individuals. Thus, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These final rules contain reporting requirements at 416.1181 and 416.1226. SSA solicited public comment on the reporting burdens on July 11, 2005 in the **Federal Register** (FR) at 70 FR 39689 and provided a 60-day comment period. An Information Collection Request has been submitted to OMB to obtain clearance of the sections cited above. SSA will publish a notice providing the OMB number and expiration date once approved.

To receive a copy of the OMB clearance package, you may call the SSA Reports Clearance Officer on 410-965-0454. Comments should be submitted and/or faxed to OMB and SSA at the following address/numbers:

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

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

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

List of Subjects in 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income, Reporting and recordkeeping requirements.

Dated: May 8, 2006.

Jo Anne B. Barnhart,
Commissioner of Social Security.

■ For the reasons set out in the preamble, we are amending subparts K and L of part 416 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

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

Subpart K—[Amended]

■ 1. The authority citation for subpart K is revised to read as follows:

Authority: Secs. 702(a)(5), 1602, 1611, 1612, 1613, 1614(f), 1621, 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1381a, 1382, 1382a, 1382b, 1382c(f), 1382j, 1383, and 1383b); sec. 211, Pub. L. 93-66, 87 Stat. 154 (42 U.S.C. 1382 note).

■ 2. The second, third and fourth sentences of § 416.1180 are revised to read as follows:

§ 416.1180 General.

* * * If you are blind or disabled, we will pay you SSI benefits and will not count the part of your income (for example, your or a family member's wages, title II benefits, or pension income) that you use or set aside to use for expenses that we determine to be reasonable and necessary to fulfill an approved plan to achieve self-support. (See §§ 416.1112(c)(9) and 1124(c)(13).) You may develop a plan to achieve self-support on your own or with our help.

■ 3. Section 416.1181 is revised to read as follows:

§ 416.1181 What is a plan to achieve self-support (PASS)?

- (a) A PASS must—
 - (1) Be designed especially for you;
 - (2) Be in writing;
 - (3) Be approved by us (a change of plan must also be approved by us);
 - (4) Have a specific employment goal that is feasible for you, that is, a goal that you have a reasonable likelihood of achieving;
 - (5) Have a plan to reach your employment goal that is viable and financially sustainable, that is, the plan—
 - (i) Sets forth steps that are attainable in order to reach your goal, and
 - (ii) Shows that you will have enough money to meet your living expenses while setting aside income or resources to reach your goal;
 - (6) Be limited to one employment goal; however, the employment goal may be modified and any changes related to the modification must be made to the plan;
 - (7) Show how the employment goal will generate sufficient earnings to substantially reduce or eliminate your dependence on SSI or eliminate your need for title II disability benefits;

Example 1: A Substantial Reduction Exists. Your SSI monthly payment amount is \$101 and your PASS employment goal earnings

will reduce your SSI payment by \$90. We may consider that to be a substantial reduction.

Example 2: A Substantial Reduction Exists. You receive a title II benefit of \$550 and an SSI payment of \$73. Your PASS employment goal will result in work over the SGA level that eliminates your title II benefit but increases your SSI payment by \$90. We may consider that a substantial reduction because your work will eliminate your title II payment while only slightly increasing your SSI payment.

Example 3: A Substantial Reduction Does Not Exist. Your SSI monthly payment amount is \$603 and your PASS employment goal earnings will reduce your SSI payment by \$90. We may not consider that to be a substantial reduction.

(8) Contain a beginning date and an ending date to meet your employment goal;

(9) Give target dates for meeting milestones towards your employment goal;

(10) Show what expenses you will have and how they are reasonable and necessary to meet your employment goal;

(11) Show what money you have and will receive, how you will use or spend it to attain your employment goal, and how you will meet your living expenses; and

(12) Show how the money you set aside under the plan will be kept separate from your other funds.

(b) You must propose a reasonable ending date for your PASS. If necessary, we can help you establish an ending date, which may be different than the ending date you propose. Once the ending date is set and you begin your PASS, we may adjust or extend the ending date of your PASS based on progress towards your goal and earnings level reached.

(c) If your employment goal is self-employment, you must include a business plan that defines the business, provides a marketing strategy, details financial data, outlines the operational procedures, and describes the management plan.

(d) Your progress will be reviewed at least annually to determine if you are following the provisions of your plan.

Subpart L—[Amended]

■ 4. The authority citation for subpart L is revised to read as follows:

Authority: Secs. 702(a)(5), 1602, 1611, 1612, 1613, 1614(f), 1621, 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1381a, 1382, 1382a, 1382b, 1382c(f), 1382j, 1383, and 1383b); sec. 211, Pub. L. 93–66, 87 Stat. 154 (42 U.S.C. 1382 note).

■ 5. Section 416.1225 is revised to read as follows:

§ 416.1225 An approved plan to achieve self-support; general.

If you are blind or disabled, we will pay you SSI benefits and will not count resources that you use or set aside to use for expenses that we determine to be reasonable and necessary to fulfill an approved plan to achieve self-support.

■ 6. Section 416.1226 is revised to read as follows:

§ 416.1226 What is a plan to achieve self-support (PASS)?

(a) A PASS must—
(1) Be designed especially for you;
(2) Be in writing;
(3) Be approved by us (a change of plan must also be approved by us);
(4) Have a specific employment goal that is feasible for you, that is, a goal that you have a reasonable likelihood of achieving;

(5) Have a plan to reach your employment goal that is viable and financially sustainable, that is, the plan—

(i) Sets forth steps that are attainable in order to reach your goal, and
(ii) Shows that you will have enough money to meet your living expenses while setting aside income or resources to reach your goal;

(6) Be limited to one employment goal; however, the employment goal may be modified and any changes related to the modification must be made to the plan;

(7) Show how the employment goal will generate sufficient earnings to substantially reduce your dependence on SSI or eliminate your need for title II disability benefits;

Example 1: A Substantial Reduction Exists. Your SSI monthly payment amount is \$101 and your PASS employment goal earnings will reduce your SSI payment by \$90. We may consider that to be a substantial reduction.

Example 2: A Substantial Reduction Exists. You receive a title II benefit of \$550 and an SSI payment of \$73. Your PASS employment goal will result in work over the SGA level that eliminates your title II benefit but increases your SSI payment by \$90. We may consider that a substantial reduction because your work will eliminate your title II payment while only slightly increasing your SSI payment.

Example 3: A Substantial Reduction Does Not Exist. Your SSI monthly payment amount is \$603 and your PASS employment goal earnings will reduce your SSI payment by \$90. We may not consider that to be a substantial reduction.

(8) Contain a beginning date and an ending date to meet your employment goal;

(9) Give target dates for meeting milestones towards your employment goal;

(10) Show what expenses you will have and how they are reasonable and necessary to meet your employment goal;

(11) Show what resources you have and will receive, how you will use them to attain your employment goal, and how you will meet your living expenses; and

(12) Show how the resources you set aside under the plan will be kept separate from your other resources.

(b) You must propose a reasonable ending date for your PASS. If necessary, we can help you establish an ending date, which may be different than the ending date you propose. Once the ending date is set and you begin your PASS, we may adjust or extend the ending date of your PASS based on progress towards your goal and earnings level reached.

(c) If your employment goal is self-employment, you must include a business plan that defines the business, provides a marketing strategy, details financial data, outlines the operational procedures, and describes the management plan.

(d) Your progress will be reviewed at least annually to determine if you are following the provisions of your plan.

[FR Doc. 06–4530 Filed 5–15–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

New Animal Drugs; Change of Sponsor; Fomepizole

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) for fomepizole solution for injection from Orphan Medical, Inc., to Jazz Pharmaceuticals, Inc. The regulations are also being amended to reflect approval of a supplemental NADA to remove a vial of saline diluent from this product.

DATES: This rule is effective May 16, 2006.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540, e-mail: melanie.berson@fda.hhs.gov.