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Drug labeler code	Firm name and address
015331	Pharmaq AS, Skogmo Industriomrade, N-7863 Overhalla, Norway.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 3. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

### § 558.575 [Amended]

■ 4. Section 558.575 is amended in paragraph (a)(2) by removing “046573” and by adding in its place “No. 015331”.

Dated: August 22, 2005.

**Steven D. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*  
[FR Doc. 05-17472 Filed 9-1-05; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF STATE

### 22 CFR Part 41

RIN 1400-AC12

### [Public Notice 5181]

### Visas: Treaty Trader, Treaty Investor, or Treaty Alien in a Specialty Occupation

**AGENCY:** State Department.

**ACTION:** Final rule.

**SUMMARY:** This rule expands the definition of treaty trader and treaty investor contained at 22 CFR 41.51 to include a new nonimmigrant category (E-3) for nonimmigrant treaty aliens coming to the United States solely to perform services in a specialty occupation. It also reorganizes existing regulatory language pertaining to treaty traders and treaty investors to make this information clearer and easier to read.

**DATES:** This rule is effective September 2, 2005.

**FOR FURTHER INFORMATION CONTACT:** Charles Robertson, Legislation and Regulations Division, Visa Services, Department of State, 2401 E Street, NW., Room L-603D, Washington, DC 20520-0106; telephone 202-663-1221; e-mail [robertsonce@state.gov](mailto:robertsonce@state.gov).

**SUPPLEMENTARY INFORMATION:**

### Why Is the Department Promulgating This Rule?

Because of the passage of a new law amending the Immigration and Nationality Act (INA). The Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, 2005, Public Law 109-13, 119 Stat. 231 was signed into law by the President on May 11, 2005. Division B, Title V, Section 501 of the Act adds a new nonimmigrant visa classification for certain treaty aliens who are coming to the United States solely to perform services in a specialty occupation. The classification will hereafter be designated the “E-3 visa.”

### Who Qualifies for the E-3 Visa?

The new E-3 visa classification currently applies only to nationals of Australia as well as their spouses and children. E-3 principal nonimmigrant aliens must be coming to the United States solely to perform services in a specialty occupation.

### Are There Other Requirements for Qualifying for an E-3 Visa?

The E-3 visa classification is numerically limited, with a maximum of 10,500 visas available annually. Spouses and children do not count against the numerical limitation nor are they required to possess the nationality of the principal. A Labor Condition Application (LCA), containing attestations by the sponsoring employer related to wages and working conditions, must be filed with and approved by the Department of Labor (DOL). At the time of visa application, the visa applicant must present the consular officer with the original or copy of the approved LCA. However, if the applicant cannot provide the original, the consular officer, at his/her discretion, may accept a certified copy of the approval. The approved LCA represents DOL's certification that the employer has met the attestation requirements of the E-3 statute.

### What Is a Specialty Occupation?

In general, a specialty occupation is one that requires theoretical and practical application of a body of knowledge in professional fields and at least the attainment of a bachelor's degree, or its equivalent, as a minimum for entry into the occupation in the United States. The Department's regulations governing E-3 visas incorporate the definitions contained in section 214(i)(1) of the Immigration and Nationality Act (INA). In order to determine what constitutes a “specialty occupation,” consular officers abroad will be guided by, and will apply,

regulatory criteria already developed by the Department of Homeland Security for the H-1B classification.

### Is It Necessary To File a Petition With the Department of Homeland Security as a Prerequisite to Visa Issuance?

No petition to the Department of Homeland Security is necessary. Instead, in the case of an employee seeking a visa, the employee will present the necessary evidence for classification directly to the consular officer at the time of visa application. Such evidence will include the original or copy of the Labor Condition Application signed by the prospective employer and approved by the Department of Labor. Procedures for the E-3 visa are similar to those established for obtaining H-1B1 classification under the U.S.-Chile and U.S.-Singapore Free Trade Agreements.

### May Spouses Work?

Yes. INA 214(e)(6) permits the spouse of a principal E nonimmigrant to engage in employment in the United States. As is the case for the spouse of a principal E-1 and E-2 nonimmigrant, the spouse of a qualified E-3 nonimmigrant may, upon admission to the United States, apply for an employment authorization document, which an employer could use to verify the spouse's employment eligibility. Such spousal employment may be in a position other than a specialty occupation.

### Regulatory Findings

#### *Administrative Procedure Act*

This final rule involves a foreign affairs function of the United States and, therefore, is not subject to the procedures required by 5 U.S.C. 553 and 554. It is exempt from review under Executive Order 12866 but has been reviewed internally by the Department to ensure consistency with the purposes thereof. This rule does not require analysis under the Regulatory Flexibility Act or the Unfunded Mandates Reform Act. It has been found not to be a major rule within the meaning of the Small Business Regulatory Enforcement Fairness Act of 1996. It will not have substantial direct effects on the States, the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this rule does not have sufficient federalism implications to warrant application of consultation provisions of Executive Orders 12372 and 13132. This rule does not impose any new reporting or recordkeeping

requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

*Regulatory Flexibility Act/Executive Order 13272: Small Business*

This rule is not subject to the notice-and-comment rulemaking provisions of the Administrative Procedure Act or any other act, and, accordingly it does not require analysis under the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) and Executive Order 13272, section 3(b).

*The Unfunded Mandates Reform Act of 1995*

Section 202 of the Unfunded Mandates Reform Act of 1995 (UFMA), Pub. L. 104-4, 109 Stat. 48, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing any rule that may result in an annual expenditure of \$100 million or more by State, local, or tribal governments, or by the private sector. This rule will not result in any such expenditure, nor will it significantly or uniquely affect small governments.

*The Small Business Regulatory Enforcement Fairness Act of 1996*

This rule is not a major rule as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking under the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104-121. This rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign based companies in domestic and import markets.

*Executive Order 12866*

The Department of State has reviewed this proposed rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866 and has determined that the benefits of the proposed regulation justify its costs. The Department does not consider the proposed rule to be an economically significant action within the scope of section 3(f)(1) of the Executive Order since it is not likely to have an annual effect on the economy of \$100 million or more or to adversely affect in a material way the economy, a sector of the economy, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities.

*Executive Orders 12372 and 13132: Federalism*

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Nor will the rule have federalism implications warranting the application of Executive Orders No. 12372 and No. 13132.

*Paperwork Reduction Act*

Applicants for E-3 visas will fill out forms that OMB has already approved, the DS-156 form (approved OMB 1405-0019) and the DS-157 form (approved OMB 1405-0134). A specialized form for E-3 applications may be developed in the future.

**List of Subjects in 22 CFR Part 41**

Immigration, Passports and visas.

**PART 41—[AMENDED]**

- 1. The authority citation for part 41 continues to read:

**Authority:** 8 U.S.C. 1104; Pub. L. 105-277, 112 Stat. 2681-795 through 2681-801.

Additional authority is derived from Section 104 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 (IIRIRA), PL-104-208, 110 Stat. 3546; as well as the Emergency Supplemental Appropriations Act for Defense, the Global War on Terror, and Tsunami Relief, 2005, P.L. 109-13, 119 Stat. 231.

- 2. Revise § 41.51 to read as follows:

**§ 41.51 Treaty trader, treaty investor, or treaty alien in a specialty occupation.**

(a) *Treaty trader.* (1) *Classification.*

An alien is classifiable as a nonimmigrant treaty trader (E-1) if the consular officer is satisfied that the alien qualifies under the provisions of INA 101(a)(15)(E)(i) and that the alien:

(i) Will be in the United States solely to carry on trade of a substantial nature, which is international in scope, either on the alien's behalf or as an employee of a foreign person or organization engaged in trade, principally between the United States and the foreign state of which the alien is a national, (consideration being given to any conditions in the country of which the alien is a national which may affect the alien's ability to carry on such substantial trade); and

(ii) Intends to depart from the United States upon the termination of E-1 status.

(2) *Employee of treaty trader.* An alien employee of a treaty trader may be

classified E-1 if the employee is in or is coming to the United States to engage in duties of an executive or supervisory character, or, if employed in a lesser capacity, the employee has special qualifications that make the services to be rendered essential to the efficient operation of the enterprise. The employer must be:

(i) A person having the nationality of the treaty country, who is maintaining the status of treaty trader if in the United States or, if not in the United States, would be classifiable as a treaty trader; or

(ii) An organization at least 50% owned by persons having the nationality of the treaty country who are maintaining nonimmigrant treaty trader status if residing in the United States or, if not residing in the United States, who would be classifiable as treaty traders.

(3) *Spouse and children of treaty trader.* The spouse and children of a treaty trader accompanying or following to join the principal alien are entitled to the same classification as the principal alien. The nationality of a spouse or child of a treaty trader is not material to the classification of the spouse or child under the provisions of INA 101(a)(15)(E).

(4) *Representative of foreign information media.* Representatives of foreign information media shall first be considered for possible classification as nonimmigrants under the provisions of INA 101(a)(15)(I), before consideration is given to their possible classification as treaty traders under the provisions of INA 101(a)(15)(E) and of this section.

(5) *Treaty country.* A treaty country is for purposes of this section a foreign state with which a qualifying Treaty of Friendship, Commerce, and Navigation or its equivalent exists with the United States. A treaty country includes a foreign state that is accorded treaty visa privileges under INA 101(a)(15)(E) by specific legislation (other than the INA).

(6) *Nationality of the treaty country.*

The authorities of the foreign state of which the alien claims nationality determine the nationality of an individual treaty trader. In the case of an organization, ownership must be traced as best as is practicable to the individuals who ultimately own the organization.

(7) *Trade.* The term "trade" as used in this section means the existing international exchange of items of trade for consideration between the United States and the treaty country. Existing trade includes successfully negotiated contracts binding upon the parties that call for the immediate exchange of items of trade. This exchange must be traceable and identifiable. Title to the

trade item must pass from one treaty party to the other.

(8) *Item of trade.* Items that qualify for trade within these provisions include but are not limited to goods, services, technology, monies, international banking, insurance, transportation, tourism, communications, and some news gathering activities.

(9) *Substantial trade.* Substantial trade for the purposes of this section entails the quantum of trade sufficient to ensure a continuous flow of trade items between the United States and the treaty country. This continuous flow contemplates numerous exchanges over time rather than a single transaction, regardless of the monetary value. Although the monetary value of the trade item being exchanged is a relevant consideration, greater weight is given to more numerous exchanges of larger value. In the case of smaller businesses, an income derived from the value of numerous transactions that is sufficient to support the treaty trader and his or her family constitutes a favorable factor in assessing the existence of substantial trade.

(10) *Principal trade.* Trade shall be considered to be principal trade between the United States and the treaty country when over 50% of the volume of international trade of the treaty trader is conducted between the United States and the treaty country of the treaty trader's nationality.

(11) *Executive or supervisory character.* The executive or supervisory element of the employee's position must be a principal and primary function of the position and not an incidental or collateral function. Executive and/or supervisory duties grant the employee ultimate control and responsibility for the enterprise's overall operation or a major component thereof.

(i) An executive position provides the employee great authority to determine policy of and direction for the enterprise.

(ii) A position primarily of supervisory character grants the employee supervisory responsibility for a significant proportion of an enterprise's operations and does not generally involve the direct supervision of low-level employees.

(12) *Special qualifications.* Special qualifications are those skills and/or aptitudes that an employee in a lesser capacity brings to a position or role that are essential to the successful or efficient operation of the enterprise.

(i) The essential nature of the alien's skills to the employing firm is determined by assessing the degree of proven expertise of the alien in the area of operations involved, the uniqueness

of the specific skill or aptitude, the length of experience and/or training with the firm, the period of training or other experience necessary to perform effectively the projected duties, and the salary the special qualifications can command. The question of special skills and qualifications must be determined by assessing the circumstances on a case-by-case basis.

(ii) Whether the special qualifications are essential will be assessed in light of all circumstances at the time of each visa application on a case-by-case basis. A skill that is unique at one point may become commonplace at a later date. Skills required to start up an enterprise may no longer be essential after initial operations are complete and are running smoothly. Some skills are essential only in the short-term for the training of locally hired employees. Long-term essentiality might, however, be established in connection with continuous activities in such areas as product improvement, quality control, or the provision of a service not generally available in the United States.

(13) *Labor disputes.* Citizens of Canada or Mexico shall not be entitled to classification under this section if the Attorney General and the Secretary of Labor have certified that:

(i) There is in progress a strike or lockout in the course of a labor dispute in the occupational classification at the place or intended place of employment; and

(ii) The alien has failed to establish that the alien's entry will not affect adversely the settlement of the strike or lockout or the employment of any person who is involved in the strike or lockout.

(b) *Treaty investor.* (1) *Classification.* An alien is classifiable as a nonimmigrant treaty investor (E'2) if the consular officer is satisfied that the alien qualifies under the provisions of INA 101(a)(15)(E)(ii) and that the alien:

(i) Has invested or is actively in the process of investing a substantial amount of capital in bona fide enterprise in the United States, as distinct from a relatively small amount of capital in a marginal enterprise solely for the purpose of earning a living; and

(ii) Is seeking entry solely to develop and direct the enterprise; and

(iii) Intends to depart from the United States upon the termination of E'2 status.

(2) *Employee of treaty investor.* An alien employee of a treaty investor may be classified E-2 if the employee is in or is coming to the United States to engage in duties of an executive or supervisory character, or, if employed in a lesser capacity, the employee has

special qualifications that make the services to be rendered essential to the efficient operation of the enterprise. The employer must be:

(i) A person having the nationality of the treaty country, who is maintaining the status of treaty investor if in the United States or, if not in the United States, who would be classifiable as a treaty investor; or

(ii) An organization at least 50% owned by persons having the nationality of the treaty country who are maintaining nonimmigrant treaty investor status if residing in the United States or, if not residing in the United States, who would be classifiable as treaty investors.

(3) *Spouse and children of treaty investor.* The spouse and children of a treaty investor accompanying or following to join the principal alien are entitled to the same classification as the principal alien. The nationality of a spouse or child of a treaty investor is not material to the classification of the spouse or child under the provisions of INA 101(a)(15)(E).

(4) *Representative of foreign information media.* Representatives of foreign information media shall first be considered for possible classification as nonimmigrants under the provisions of INA 101(a)(15)(I), before consideration is given to their possible classification as nonimmigrants under the provisions of INA 101(a)(15)(E) and of this section.

(5) *Treaty country.* A treaty country is for purposes of this section a foreign state with which a qualifying Treaty of Friendship, Commerce, and Navigation or its equivalent exists with the United States. A treaty country includes a foreign state that is accorded treaty visa privileges under INA 101(a)(15)(E) by specific legislation (other than the INA).

(6) *Nationality of the treaty country.* The authorities of the foreign state of which the alien claims nationality determine the nationality of an individual treaty investor. In the case of an organization, ownership must be traced as best as is practicable to the individuals who ultimately own the organization.

(7) *Investment.* Investment means the treaty investor's placing of capital, including funds and other assets, at risk in the commercial sense with the objective of generating a profit. The treaty investor must be in possession of and have control over the capital invested or being invested. The capital must be subject to partial or total loss if investment fortunes reverse. Such investment capital must be the investor's unsecured personal business capital or capital secured by personal assets. Capital in the process of being

invested or that has been invested must be irrevocably committed to the enterprise. The alien has the burden of establishing such irrevocable commitment given to the particular circumstances of each case. The alien may use any legal mechanism available, such as by placing invested funds in escrow pending visa issuance, that would not only irrevocably commit funds to the enterprise but that might also extend some personal liability protection to the treaty investor.

(8) *Bona fide enterprise.* The enterprise must be a real and active commercial or entrepreneurial undertaking, producing some service or commodity for profit and must meet applicable legal requirements for doing business in the particular jurisdiction in the United States.

(9) *Substantial amount of capital.* A substantial amount of capital constitutes that amount that is:

(i)(A) Substantial in the proportional sense, *i.e.*, in relationship to the total cost of either purchasing an established enterprise or creating the type of enterprise under consideration;

(B) Sufficient to ensure the treaty investor's financial commitment to the successful operation of the enterprise; and

(C) Of a magnitude to support the likelihood that the treaty investor will successfully develop and direct the enterprise.

(ii) Whether an amount of capital is substantial in the proportionality sense is understood in terms of an inverted sliding scale; *i.e.*, the lower the total cost of the enterprise, the higher, proportionately, the investment must be to meet these criteria.

(10) *Marginal enterprise.* A marginal enterprise is an enterprise that does not have the present or future capacity to generate more than enough income to provide a minimal living for the treaty investor and his or her family. An enterprise that does not have the capacity to generate such income but that has a present or future capacity to make a significant economic contribution is not a marginal enterprise. The projected future capacity should generally be realizable within five years from the date the alien commences normal business activity of the enterprise.

(11) *Solely to develop and direct.* The business or individual treaty investor does or will develop and direct the enterprise by controlling the enterprise through ownership of at least 50% of the business, by possessing operational control through a managerial position or other corporate device, or by other means.

(12) *Executive or supervisory character.* The executive or supervisory element of the employee's position must be a principal and primary function of the position and not an incidental or collateral function. Executive and/or supervisory duties grant the employee ultimate control and responsibility for the enterprise's overall operation or a major component thereof.

(i) An executive position provides the employee great authority to determine policy of and direction for the enterprise.

(ii) A position primarily of supervisory character grants the employee supervisory responsibility for a significant proportion of an enterprise's operations and does not generally involve the direct supervision of low-level employees.

(13) *Special qualifications.* Special qualifications are those skills and/or aptitudes that an employee in a lesser capacity brings to a position or role that are essential to the successful or efficient operation of the enterprise.

(i) The essential nature of the alien's skills to the employing firm is determined by assessing the degree of proven expertise of the alien in the area of operations involved, the uniqueness of the specific skill or aptitude, the length of experience and/or training with the firm, the period of training or other experience necessary to perform effectively the projected duties, and the salary the special qualifications can command. The question of special skills and qualifications must be determined by assessing the circumstances on a case-by-case basis.

(ii) Whether the special qualifications are essential will be assessed in light of all circumstances at the time of each visa application on a case-by-case basis. A skill that is unique at one point may become commonplace at a later date. Skills required to start up an enterprise may no longer be essential after initial operations are complete and are running smoothly. Some skills are essential only in the short-term for the training of locally hired employees. Long-term essentiality might, however, be established in connection with continuous activities in such areas as product improvement, quality control, or the provision of a service not generally available in the United States.

(14) *Labor disputes.* Citizens of Canada or Mexico shall not be entitled to classification under this section if the Attorney General and the Secretary of Labor have certified that:

(i) There is in progress a strike or lockout in the course of a labor dispute in the occupational classification at the

place or intended place of employment; and

(ii) The alien has failed to establish that the alien's entry will not affect adversely the settlement of the strike or lockout or the employment of any person who is involved in the strike or lockout.

(c) Nonimmigrant E-3 treaty aliens in specialty occupations. (1) *Classification.* An alien is classifiable as a nonimmigrant treaty alien in a specialty occupation if the consular officer is satisfied that the alien qualifies under the provisions of INA 101(a)(15)(E)(iii) and that the alien:

(i) Possesses the nationality of the country statutorily designated for treaty aliens in specialty occupation status;

(ii) Satisfies the requirements of INA 214(i)(1) and the corresponding regulations defining specialty occupation promulgated by the Department of Homeland Security;

(iii) Presents to a consular officer a copy of the Labor Condition Application signed by the employer and approved by the Department of Labor, and meeting the attestation requirements of INA Section 212(t)(1);

(iv) Presents to a consular officer evidence of the alien's academic or other qualifying credentials as required under INA 214(i)(1), and a job offer letter or other documentation from the employer establishing that upon entry into the United States the applicant will be engaged in qualifying work in a specialty occupation, as defined in paragraph (c)(1)(ii) of this section, and that the alien will be paid the actual or prevailing wage referred to in INA 212(t)(1);

(v) Has a visa number allocated under INA 214(g)(11)(B); and,

(vi) Intends to depart upon the termination of E-3 status.

(2) *Spouse and children of treaty alien in a specialty occupation.* The spouse and children of a treaty alien in a specialty occupation accompanying or following to join the principal alien are, if otherwise admissible, entitled to the same classification as the principal alien. A spouse or child of a principal E-3 treaty alien need not have the same nationality as the principal in order to be classifiable under the provisions of INA 101(a)(15)(E). Spouses and children of E-3 principals are not subject to the numerical limitations of INA 214(g)(11)(B).

Dated: July 14, 2005.

**Maura Harty,**

*Assistant Secretary for Consular Affairs,  
Department of State.*

[FR Doc. 05-17622 Filed 9-1-05; 8:45 am]

**BILLING CODE 4710-06-P**