

COORDINATION OF RETIREMENT AND EFFECTIVE DATES TABLE—Continued

Existing approved standard	Requirement to be retired or replaced	Proposed standard	New requirement to be implemented	Date for concurrent retirement and implementation
PER-004-1	R3 R4		R2.1	
PER-002-0	R4	PER-005-1	R3	1st day of 1st calendar quarter after regulatory approval.
PER-004-1	R2		R1	
PER-004-1	R1	PER-004-2	R1	1st day of 1st calendar quarter after regulatory approval.
	R5		R2	
N/A	N/A	PER-005-1	R3.1	1st day of 1st calendar quarter 36 months after regulatory approval.

[FR Doc. 2010-29717 Filed 11-24-10; 8:45 am]
BILLING CODE 6717-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

[Docket No. FDA-2010-N-0002]

New Animal Drugs; Change of Sponsor's Name and Address

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's name from Belcher Pharmaceuticals, Inc., to Belcher Pharmaceuticals, LLC. The sponsor's mailing address will also be changed.

DATES: This rule is effective November 26, 2010.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855; 240-276-8300, e-mail: steven.vaughn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Belcher Pharmaceuticals, Inc., 12393 Belcher Rd., suite 420, Largo, FL 33773 has informed FDA that it has changed its name and address to Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777. Accordingly, the Agency is amending the regulations in 21 CFR 510.600 to reflect this change.

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 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

■ 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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), revise the entry for "Belcher Pharmaceuticals, Inc."; and in the table in paragraph (c)(2), revise the entry for "062250" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *
(c) * * *
(1) * * *

Firm name and address	Drug labeler code
* * * * *	*
Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777.	062250
* * * * *	*
(2) * * *	
Drug labeler code	Firm name and address
* * * * *	
062250	Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777.
* * * * *	

Dated: November 19, 2010.

Elizabeth Rettie,
Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2010-29693 Filed 11-24-10; 8:45 am]
BILLING CODE 4160-01-P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management, Regulation and Enforcement

30 CFR Part 285

[Docket ID: BOEM-2010-0045]

RIN 1010-AD71

Renewable Energy Alternate Uses of Existing Facilities on the Outer Continental Shelf—Acquire a Lease Noncompetitively

AGENCY: Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE), Interior.

ACTION: Direct Final rule.

SUMMARY: BOEMRE is revising regulations that pertain to noncompetitive acquisition of an Outer Continental Shelf (OCS) renewable energy lease. We are taking this action because the current regulations covering noncompetitive leasing of an OCS renewable energy lease and an unsolicited request for an OCS renewable energy lease are inconsistent. This rulemaking will make the two processes consistent with each other by eliminating an extra step in the noncompetitive leasing process.

DATES: Effective Date: This rule becomes effective on January 25, 2011 unless BOEMRE publishes a notice withdrawing this rule before that date.

Comment Due Date: Submit comments on the direct final rule by December 27, 2010.

FOR FURTHER INFORMATION CONTACT: Timothy Redding at (703) 787-1219.

ADDRESSES: You may submit comments on the rulemaking by any of the following methods. Please use the Regulation Identifier Number (RIN) 1010-AD71 as an identifier in your message. See also Public Availability of Comments under Procedural Matters.

- Federal eRulemaking Portal: <http://www.regulations.gov>. In the entry titled "Enter Keyword or ID," enter BOEM-2010-0045, then click search. Follow the instructions to submit public comments and view supporting and related materials available for this rulemaking. BOEMRE will post all comments.

- Mail or hand-carry comments to the Department of the Interior; Bureau of Ocean Energy Management, Regulation and Enforcement; Attention: Regulations and Standards Branch (RSB); 381 Elden Street, MS-4024, Herndon, Virginia 20170-4817. Please reference "Acquire a Lease Noncompetitively, 1010-AD71" in your comments and include your name and address.

SUPPLEMENTARY INFORMATION

Background

The regulations at 30 CFR part 285 cover renewable energy and alternative uses of existing facilities on the OCS. This direct final rule revises the regulations at §§ 285.231 and 285.232. The regulations at § 285.231 cover unsolicited requests for noncompetitive leases. The regulations at § 285.232 cover acquisition of noncompetitive leases in response to a Request for Interest (RFI) or a Call for Information and Nomination (Call). The process outlined in these two sections is currently inconsistent now for awarding of noncompetitive leases.

As currently written, § 285.231 allows for the awarding of a noncompetitive lease after BOEMRE receives an unsolicited request for a noncompetitive lease, and after BOEMRE determines that there is no competitive interest after publishing a single notice of a request for interest relating to the unsolicited request for a noncompetitive lease. As currently written, § 285.232 provides that if a respondent to an RFI or a Call submits an area of leasing interest to BOEMRE for which no other nominations are submitted, BOEMRE may offer a lease through a noncompetitive process. However, the process requires publication of a second RFI notice to confirm the absence of competition before proceeding with the noncompetitive process. We believe that this requirement for a second notice is unnecessarily redundant and at odds with the noncompetitive process prescribed for cases in which a party

submits an unsolicited request for an OCS renewable energy lease, where BOEMRE is required to publish only a single notice.

To remedy this inconsistency, BOEMRE is revising § 285.231(d)(1) to say that we will publish in the **Federal Register** a notice that there is no competitive interest. We will also revise § 285.232(c) to cite § 285.231(d) through (i) instead of the current § 285.231(b) through (i).

This is a direct final rulemaking with request for comments. We have provided a 30-day comment period for this direct final rule. We believe that 30 days is sufficient time for comments because this rulemaking is noncontroversial, and the revision was recommended by the American Wind Energy Association, the Atlantic Offshore Wind Energy Consortium (established by the Secretary of the Interior), and individual coastal states. If we receive no significant adverse comment during the 30-day comment period, this rule will go into effect 30 days after the end of the comment period. However, if a significant adverse comment is received, BOEMRE will withdraw the rule by publishing a notice of withdrawal in the **Federal Register** within 30 days after the public comment period closes and will publish a notice of proposed rulemaking. A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach or would be ineffective and unacceptable without a change.

Procedural Matters

Regulatory Planning and Review (Executive Order (E.O.) 12866)

This rule is not a significant rule as determined by the Office of Management and Budget (OMB) and is not subject to review under E.O. 12866.

(1) This rule will not have an annual effect of \$100 million or more on the economy. It will not adversely affect in a material way the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency. The rule is intended to eliminate unnecessary redundancy and inefficiency.

(3) This rule will not alter the budgetary effects of entitlements, grants, user fees, or loan programs or the rights or obligations of their recipients.

(4) This rule will not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in E.O. 12866.

Regulatory Flexibility Act

The Department of the Interior certifies that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The Department prepared a regulatory flexibility analysis for 30 CFR part 285, and concluded that the regulations will impact a substantial number of small entities but will not have a significant economic impact on the small entities in comparison to the impacts on large entities. That analysis was discussed in detail in the Notice of Proposed Rulemaking published in the **Federal Register** on July 9, 2008 (73 FR 39376).

The North American Industry Classification System (NAICS) code for the industries affected by this rule is 221119 (Other Electric Power Generation). The definition for this code is:

- "This U.S. industry comprises establishments primarily engaged in operating electric power generation facilities (except hydroelectric, fossil fuel, nuclear). These facilities convert other forms of energy, such as solar, wind, or tidal power, into electrical energy. The electric energy produced in these establishments is provided to electric power transmission systems or to electric power distribution systems."

It is possible that this rule could eventually affect entities that produce hydrogen and fall under NAICS Code 325120 (Industrial Gas Manufacturing). The definition for this code is:

- "This industry comprises establishments primarily engaged in manufacturing industrial organic and inorganic gases in compressed, liquid, or solid forms."

Given the original findings of the regulatory flexibility analysis done for 30 CFR part 285, as well as the minor adjustment to the renewable energy leasing process that is entailed, the revised rule will not have a significant effect on a substantial number of small entities.

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the actions of BOEMRE, call 1-888-734-3247. You may comment to the Small Business

Administration without fear of retaliation. Allegations of discrimination/retaliation filed with the Small Business Administration will be investigated for appropriate action.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801 *et seq.*). This rule:

- a. Will not have an annual effect on the economy of \$100 million or more.
- b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.
- c. Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. The requirements will apply indiscriminately to entities operating on the OCS to lease and develop renewable energy under 30 CFR part 285.

Unfunded Mandate Reform Act of 1995

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than \$100 million per year. The rule will not have a significant or unique effect on State, local, or tribal governments or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*) is not required.

Takings Implication Assessment (E.O. 12630)

Under the criteria in E.O. 12630, this rule does not have significant takings implications. The rule is not a governmental action capable of interference with constitutionally protected property rights. A Takings Implication Assessment is not required.

Federalism (E.O. 13132)

Under the criteria in E.O. 13132, this rule does not have federalism implications. This rule will not substantially and directly affect the relationship between the Federal and State governments. To the extent that State and local governments have a role in OCS activities, this rule will not affect that role. A Federalism Assessment is not required.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

- (a) Meets the criteria of section 3(a) requiring that all regulations be

reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

- (b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (E.O. 13175)

Under the criteria in E.O. 13175, we have evaluated this rule and determined that it has no substantial effects on federally recognized Indian tribes.

Paperwork Reduction Act (PRA)

This rulemaking contains no new reporting or recordkeeping requirements; therefore, an Office of Management and Budget (OMB) submission under the PRA (44 U.S.C. 3501 *et seq.*) is not required. The PRA provides that an agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information and assigns a control number, you are not required to respond. The revisions in this rulemaking refer to, but do not change, information collection requirements in 30 CFR part 285. The OMB approved the referenced information collection requirements under OMB Control Number 1010-0176 (expiration 3/31/2013).

National Environmental Policy Act of 1969

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. BOEMRE has analyzed this rule under the criteria of the National Environmental Policy Act and 516 Departmental Manual 15. This rule meets the criteria set forth in 516 Departmental Manual 2 (Appendix 1.10) for a Departmental "Categorical Exclusion" in that this proposed rule is "* * * of an administrative, financial, legal, technical, or procedural nature and whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis * * * This rule also meets the criteria set forth in 516 Departmental Manual 15.4(C)(1) for a BOEMRE "Categorical Exclusion" in that its impacts are limited to administration, economic or technological effects. Further, BOEMRE has analyzed this rule to determine if it meets any of the extraordinary circumstances that would require an environmental assessment or an environmental impact statement as set forth in 516 Departmental Manual 2.3, and Appendix 2. BOEMRE concluded

that this rule does not meet any of the criteria for extraordinary circumstances as set forth in 516 Departmental Manual 2 (Appendix 2).

Data Quality Act

In developing this rule, BOEMRE did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106-554, app. C section 515, 114 Stat. 2763, 2763A-153-154).

Effects on the Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. A Statement of Energy Effects is not required.

Clarity of This Regulation

We are required by E.O. 12866, E.O. 12988, and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

- (a) Be logically organized;
- (b) Use the active voice to address readers directly;
- (c) Use clear language rather than jargon;
- (d) Be divided into short sections and sentences; and
- (e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Public Availability of Comments

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

List of Subjects in 30 CFR Part 285

Continental shelf, Environmental protection, Public lands.

Dated: November 12, 2010.

Wilma A. Lewis,

Assistant Secretary for Land and Minerals Management.

■ For the reasons stated in the preamble, the Bureau of Ocean Energy Management, Regulation and Enforcement (BOEMRE) amends 30 CFR part 285 as follows:

**PART 285—RENEWABLE ENERGY
ALTERNATE USES OF EXISTING
FACILITIES ON THE OUTER
CONTINENTAL SHELF**

■ The authority citation for part 285 continues to read as follows:

Authority: 43 U.S.C. 1331 *et seq.*, 43 U.S.C. 1337.

■ In § 285.231, revise the section heading and paragraph (d)(1) to read as follows:

§ 285.231 How will BOEMRE process my unsolicited request for a noncompetitive lease?

* * * * *

(d) * * *

(1) We will publish in the **Federal Register** a notice that there is no competitive interest; and

* * * * *

■ Amend § 285.232 by revising paragraph (c) to read as follows:

§ 285.232 May I acquire a lease noncompetitively after responding to a Request for Interest or Call for Information and Nominations under § 285.213?

* * * * *

(c) After receiving the acquisition fee, BOEMRE will follow the process outlined in § 285.231(d) through (i).

[FR Doc. 2010-29761 Filed 11-23-10; 4:15 pm]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 108

[Docket ID: DOD-2009-OS-0036]

RIN 0790-AI52

Health Care Eligibility Under the Secretarial Designee Program and Related Special Authorities

AGENCY: Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: This rule establishes policy and assigns responsibilities for health care eligibility under the Secretarial Designee Program. It also implements the requirement that the United States receive reimbursement for inpatient

health care provided in the United States to foreign military or diplomatic personnel or their dependents, except in certain cases covered by Reciprocal Health Care Agreements (RHCAs) between the Department of Defense and a foreign country.

DATES: *Effective Date:* This rule is effective December 27, 2010.

FOR FURTHER INFORMATION CONTACT: Col Michael Skidmore, (703) 614-4157.

SUPPLEMENTARY INFORMATION: This rule establishes policy and assigns responsibilities under 10 U.S.C. 1074(c) for health care eligibility under the Secretarial Designee Program. It also implements the requirement of 10 U.S.C. 2559 that the United States receive reimbursement for inpatient health care provided in the United States to foreign military or diplomatic personnel or their dependents, except in certain cases covered by Reciprocal Health Care Agreements (RHCAs) between the Department of Defense and a foreign country.

Comments

The Department of Defense published a proposed rule on April 9, 2010 (75 FR 18138-18142). One public comment was received that was in full support of the rule.

Other changes have been incorporated into the rule text based on additional internal coordination within the Department to provide clarity. The responsibilities of the Assistant Secretary of Defense for Health Affairs under the proposed rule moved to the Under Secretary of Defense for Personnel and Readiness.

Executive Order 12866, “Regulatory Planning and Review”

It has been certified that 32 CFR part 108 does not:

(1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.

Sec. 202, Pub. L. 104-4, “Unfunded Mandates Reform Act”

It has been certified that 32 CFR part 108 does not contain a Federal mandate that may result in the expenditure by State, local and tribal governments, in aggregate, or by the private sector, of \$100 million or more in any one year.

Public Law 96-354, “Regulatory Flexibility Act” (5 U.S.C. 601)

It has been certified that 32 CFR part 108 is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities.

Public Law 96-511, “Paperwork Reduction Act” (44 U.S.C. Chapter 35)

It has been certified that 32 CFR part 108 does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

Executive Order 13132, “Federalism”

It has been certified that 32 CFR part 108 does not have federalism implications, as set forth in Executive Order 13132. This rule does not have substantial direct effects on:

(1) The States;

(2) The relationship between the National Government and the States; or

(3) The distribution of power and responsibilities among the various levels of Government.

List of Subjects in 32 CFR Part 108

Diplomatic personnel, Health care, Military personnel.

■ Accordingly, 32 CFR part 108 is added to read as follows.

PART 108—HEALTH CARE ELIGIBILITY UNDER THE SECRETARIAL DESIGNEE PROGRAM AND RELATED SPECIAL AUTHORITIES

Sec.

108.1 Purpose.

108.2 Applicability.

108.3 Definition.

108.4 Policy.

108.5 Eligible senior officials of the U.S. Government.

108.6 Responsibilities.

Authority: 10 U.S.C. 1074(c); 10 U.S.C. 2559.

§ 108.1 Purpose.

This part:

(a) Establishes policy and assigns responsibilities under 10 U.S.C. 1074(c) for health care eligibility under the Secretarial Designee Program.

(b) Implements the requirement of 10 U.S.C. 2559 that the United States receive reimbursement for inpatient