

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 902

50 CFR Part 679

[Docket No. 990407088-9199-02; I.D. 030999A]

RIN 0648-AK69

Fisheries of the Exclusive Economic Zone Off Alaska; License Limitation Program

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: NMFS issues a final rule that amends regulations implementing the License Limitation Program (LLP) by adding an application process and a transfer process for LLP licenses. This action is necessary to complete final implementation of the LLP, and is intended to further the objectives of the Fishery Management Plan (FMP) for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area, the FMP for Groundfish of the Gulf of Alaska, and the FMP for the Commercial King and Tanner Crab Fisheries in the Bering Sea/Aleutian Islands.

DATES: Effective September 7, 1999.

ADDRESSES: Comments regarding the collection-of-information requirements contained in this final rule should be sent to Susan J. Salveson, Assistant Regional Administrator for Sustainable Fisheries, Sustainable Fisheries Division, Alaska Region, NMFS, 709 West 9th Street, Room 453, Juneau, AK 99801, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (Attention: NOAA Desk Officer).

FOR FURTHER INFORMATION CONTACT: John Lepore, 907-586-7228.

SUPPLEMENTARY INFORMATION: The U.S. groundfish fisheries of the Gulf of Alaska (GOA) and the Bering Sea and Aleutian Islands Management Area (BSAI) in the exclusive economic zone (EEZ) are managed by NMFS pursuant to the FMPs for groundfish in the respective management areas. The commercial king crab and Tanner crab fisheries in the Bering Sea and the Aleutian Islands Area are managed by the State of Alaska with Federal oversight, pursuant to the FMP for those fisheries. The FMPs were prepared by the North Pacific Fishery Management

Council (Council), pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801, *et seq.*, and are implemented by regulations at 50 CFR part 679. General regulations at 50 CFR part 600 also apply.

Fishing under the LLP for the commercial groundfish fisheries in the EEZ of the GOA and the BSAI and the commercial king crab and Tanner crab fisheries in the EEZ of the Bering Sea and the Aleutian Islands Area is scheduled to begin January 1, 2000. The LLP replaces the Vessel Moratorium Program, which expires on December 31, 1999 (64 FR 3651, January 25, 1999).

This rule establishes the application and transfer processes for LLP licenses. The proposed rule, on which this rule is based, was published April 19, 1999 (64 FR 19113). Further information on the purpose of and eligibility criteria for the LLP can be found in the preamble to the final rule implementing Amendment 39 to the FMP for the Groundfish Fishery of the BSAI, Amendment 41 to the FMP for Groundfish of GOA, and Amendment 5 to the FMP for the Commercial King and Tanner Crab Fisheries in the Bering Sea/Aleutian Islands (63 FR 52642, October 1, 1998).

Application Process for LLP Licenses

This rule provides that a limited application period of no less than 90 days will be specified by notification in the *Federal Register*. A limited application period means that an applicant will have a specific time period to apply for an LLP license. An application for an LLP license postmarked after the ending date of the application period will be denied. NMFS anticipates that this application period will begin in August or September 1999.

NMFS currently is compiling a database containing information on vessels that participated in the groundfish and crab fisheries during the qualifying periods for LLP licenses. Sources of information for this database include weekly production reports and observer reports from NMFS and fish tickets, processor annual reports, and vessel registration information from the State of Alaska. NMFS will create the official LLP record from only complete and verifiable information from the database. The official LLP record will be presumed to be correct for the purpose of determining eligibility. An applicant that includes information in an application that is inconsistent with information in the official LLP record will have the burden of proving that the

information submitted in the application is correct.

NMFS will develop a summary of qualifications from the official LLP record for each person who appears to be eligible for an LLP license. NMFS will send a copy of the summary of qualifications along with an application form to these persons. Applications also will be provided to persons on request. An applicant who agrees with the summary of qualifications may include that information in his or her application. Using the information from the summary of qualifications will expedite application processing because the information will be consistent with information in the official LLP record.

An applicant may include information in the application other than that contained in the summary of qualifications if an applicant disagrees with the information provided in the summary of qualifications or if that information is incomplete. However, the applicant must prove that the information submitted in the application that is inconsistent with, or in addition to, information provided in the summary of qualifications is correct.

An applicant can meet this burden of proof by submitting evidence along with the application to verify the inconsistent or additional information provided on the application form. Information provided on the application form that cannot be verified with this evidence will not be accepted. The applicant will be notified that the information provided in the application cannot be verified and will be provided with a 60-day evidentiary period to submit further evidence to prove the information contained in the application is correct. This 60-day period will also be provided for an applicant to provide further information if the information provided on his or her application form is incomplete. Only one 60-day period will be provided for each applicant.

Examples of evidence that can be used to verify information inconsistent with or in addition to information provided in the summary of qualifications are: (1) State fish tickets or weekly production reports to verify documented harvests not found in the official LLP record, (2) an abstract of title or sales contract to verify vessel ownership, and (3) a written contract transferring or retaining the fishing history of a qualified vessel. Other forms of evidence will be accepted if that evidence verifies submitted information.

Information provided on an application form that cannot be verified at the conclusion of the 60-day evidentiary period will not be accepted, and claims based on that information

will be denied. At that time, NMFS will issue an initial administrative determination (IAD) indicating why those claims are denied. An applicant may appeal the IAD pursuant to the provisions of § 679.43.

An applicant who held a license the previous year will be eligible for a non-transferable license pending the final resolution of his or her claims pursuant to the license renewal provisions of 5 U.S.C. 558. This non-transferable license will be issued to an applicant in the IAD, will authorize the applicant to deploy a vessel to conduct directed fishing for license limitation groundfish or crab species as specified on the license, and will have specific endorsements and designations based on verified and unverified claims of the applicant. The non-transferable license will be effective until final agency action.

If any of an applicant's claims are in dispute, the entire license received by the applicant will be non-transferable until final resolution of all the disputed claims, including portions of the license that are based on claims that can be verified. This will prevent an applicant from transferring away the portion of the license that was based on verified claims and keeping the non-transferable portion based on disputed claims. Such transfer activity could lead to additional participants in the affected fisheries. A non-transferable license expires on final agency action. At that time, the person who appealed will either receive a transferable license, or no license at all, depending on the final agency action.

Transfer Process for LLP Licenses

The transfer process for LLP licenses will enable a license holder to request a transfer of an LLP license to any person that meets the eligibility requirements. The following requirements must be met for eligibility: The designated transferee must meet the U.S. Citizenship requirements of Chapter 121, Title 46, U.S.C., the parties to the transfer cannot have any fines, civil penalties, other payments due and outstanding, or outstanding permit sanctions resulting from Federal fishing violations, and the transfer cannot cause the designated transferee to exceed the license cap in § 679.7(i)(1).

A complete transfer application must be submitted to the Administrator, Alaska Region, NMFS (Regional Administrator), for approval before a transfer can occur. Transfer application forms will be available on request. An incomplete application will be returned to the applicant with identification of specific information that is necessary to make the application complete. Specific

information for a transfer application includes (1) identification information for all parties to the transfer, (2) evidence of the eligibility of the designated transferee to document a fishing vessel, (3) a copy of the contract or sales agreement for the transfer, (4) the signatures of the parties to the transfer, and (5) identification information for the vessel to be deployed based on the transferred license. A transferee may choose not to designate a vessel at the time of transfer, in which case the license will be transferred but it cannot be used to deploy a vessel until one is designated. A designated vessel means any vessel named on the license, including the same vessel that was named on the license before the transfer.

The rule also provides for transfer requests by court order, by operation of law, or as part of a security agreement. This provision will accommodate a transfer that is not voluntarily requested by the permit holder. Under those circumstances, the Regional Administrator will review the information in the transfer application or other documents and determine whether the requested transfer conflicts with other provisions of the LLP regulations or other applicable law (e.g., transfer to a person who could not document a fishing vessel under Chapter 121, Title 46, U.S.C.). If the Regional Administrator determines that the transfer (1) is not in conflict with other provisions of the LLP and (2) is not voluntary, the transfer will be allowed notwithstanding the annual limit on LLP license transfers explained here.

A request to change the vessel designated on the license is closely related to a transfer of a license between two persons. A license holder may deploy only the vessel designated on the license; therefore, a person must request a change of that designated vessel if the license holder plans to deploy a vessel other than the one currently designated on the license. A request to change the vessel designated on the license can be done at the same time and on the same form as the license transfer. Alternatively, the transferee may choose to retain the vessel designated on the license before the transfer. These designations are considered part of the transfer and will not count separately towards the annual transfer limit explained here. If the transferee chooses not to designate a vessel at time of transfer (i.e., specifies "none" on the transfer form), the license cannot be used until a vessel is designated. The vessel designation that occurs after a transfer in which a person designates no

vessel will not count separately towards the annual limit on transfers. Otherwise, a request to change the vessel designated on the license will be counted towards the annual limit on transfers.

Finally, a license holder is limited to one voluntary license transfer (or one designated vessel change not accompanying a transfer) per calendar year. This limit is designed to restrict the incidence of intraseason movement of licenses among operators and vessels. Intraseason movement of licenses was identified by the Council as behavior that could significantly contribute to overcapacity and excess effort in the affected fisheries.

Comments on and Changes to the Proposed Rule

NMFS received no comments on the proposed rule and made only non-substantive changes to the regulatory text as proposed. Besides changes for clarity and readability, a provision was added at § 679.4(k)(7)(v) indicating the transfer process must be used to change a vessel designated on an LLP license. The preamble to the proposed rule indicated that the transfer process would have to be used to change the vessel designated on the license. This activity, under both the proposed and final rules, would count toward the voluntary transfer limit.

NOAA codifies its OMB control numbers for information collection at 15 CFR part 902. Part 902 collects and displays the control numbers assigned to information collection requirements of NOAA by OMB pursuant to the Paperwork Reduction Act (PRA). This final rule codifies OMB control number 0648-0334 for § 679.4(k)(6) and (k)(7).

Under NOAA Administrative Order 25-11, dated December 17, 1990, the Under Secretary for Oceans and Atmosphere has delegated to the Assistant Administrator for Fisheries, NOAA, the authority to sign material for publication in the **Federal Register**.

Classification

The Regional Administrator has determined that this rule is necessary for the conservation and management of the groundfish fisheries off Alaska and the Commercial king and Tanner crab fisheries in the Bering Sea and the Aleutian Islands and that it is consistent with the Magnuson-Stevens Fishery Conservation and Management Act and other applicable law.

This final rule has been determined to be not significant for purposes of E.O. 12866.

The Chief Counsel for Regulation, Department of Commerce, certified to

the Chief Counsel for Advocacy of the Small Business Administration when this rule was proposed that, if adopted as proposed, it would not have a significant economic impact on a substantial number of small entities. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not prepared.

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to penalty for failure to comply with a collection of information, subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

This rule contains a revised collection-of-information requirement subject to the Paperwork Reduction Act (PRA). This revision has approved by OMB under control number 0648-0334. The public reporting burden for this collection of information is estimated to average 2.5 hours per response for an application for initial issuance, 1 hour per response for an application for transfer, and 4 hours per response for an appeal. These response times include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these burden estimates or any other aspect of the data requirements, including suggestions for reducing the burden, to NMFS, P.O. Box 21668, Juneau, AK 99802, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (Attn: NOAA Desk Officer). OMB approved the original collection of information requirement for the LLP under OMB control number 0648-0334. Please refer to this number in any correspondence regarding this request.

List of Subjects

15 CFR Part 902

Reporting and recordkeeping requirements.

50 CFR Part 679

Alaska, Fisheries, Reporting and recordkeeping requirements.

Dated: July 30, 1999.

Andrew A. Rosenberg,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 15 CFR part 902, chapter IX, and 50 CFR part 648, chapter VI, are amended as follows:

15 CFR Chapter IX

PART 902—NOAA INFORMATION COLLECTION REQUIREMENTS UNDER THE PAPERWORK REDUCTION ACT; OMB CONTROL NUMBERS

1. The authority citation for part 902 continues to read as follows:

Authority: 44 U.S.C. 3501 et seq.

2. In § 902.1, the table in paragraph (b) is amended by adding under 50 CFR the following entries in numerical order:

§ 902.1 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

Table with 5 columns: CFR part or section where the information collection requirement is located, Current OMB control (all numbers begin with 0648), and asterisks. Rows include 50 CFR, 679.4(k)(6)(iii), 679.4(k)(6)(iv), 679.4(k)(7)(iii).

50 CFR Chapter VI

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

1. The authority citation for part 679 continues to read as follows:

Authority: 16 U.S.C. 773 et seq., 1801 et seq., and 3631 et seq.

2. In § 679.2, the definition for "Official LLP record" is added in alphabetical order to read as follows:

§ 679.2 Definitions.

Official LLP record means the information prepared by the Regional Administrator about vessels that were used to participate in the groundfish and crab fisheries during the qualifying periods for the License Limitation Program (LLP). Information in the official LLP record includes vessel ownership information, documented harvests made from vessels during the qualification periods, and vessel characteristics. The official LLP record is presumed to be correct for the purpose of determining eligibility for licenses. An applicant for a license under the LLP will have the burden of proving that information submitted in

an application that is inconsistent with the official LLP record is correct.

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3. In § 679.4, reserved paragraphs (k)(6) and (k)(7) are added to read as follows:

§ 679.4 Permits.

* * * * *

(k) * * *

(6) Application for a groundfish license or a crab species license. (i) General. The Regional Administrator will issue a groundfish license or a crab species license to an applicant if a complete application is submitted by or on behalf of the applicant during the specified application period, and if that applicant meets all the criteria for eligibility in paragraph (k) of this section. An application that is postmarked or delivered after the ending date for the application period for the License Limitation Program specified in the Federal Register will be denied. An application form will be sent to the last known address of a person identified as an eligible applicant by the official LLP record. An application form may be requested from the Regional Administrator.

(ii) Application period. An application period of no less than 90 days will be specified by notification in the Federal Register and other information sources deemed appropriate by the Regional Administrator.

(iii) Contents of application. To be complete, an application for a groundfish license or a crab species license must be signed by the applicant, or the individual representing the applicant, and contain the following, as applicable:

(A) Name, business address, telephone number, and FAX number of the applicant;

(B) Name, state registration number (e.g., ADF&G number), and, if applicable, the USCG documentation number of the vessel being used as the basis for eligibility for a license; and name, state registration number (e.g., ADF&G number), and, if applicable, the USCG documentation number of the vessel to be deployed with the license if different than the vessel used as the basis of eligibility for a license;

(C) Name of the managing company, if any;

(D) Valid evidence of the documented harvests that are the basis of eligibility for a license, including harvest area, gear used, date of landing, and, if applying for a crab species license, species;

(E) Valid evidence of LOA on June 24, 1992, of the vessel used as the basis of eligibility for a license, except if that

vessel was under reconstruction on that date, valid evidence of LOA on the date reconstruction was completed and valid evidence of when reconstruction began and ended;

(F) Valid evidence of LOA on June 17, 1995, of the vessel used as the basis of eligibility for a license, except if that vessel was under reconstruction on that date, valid evidence of LOA on the date reconstruction was completed, and valid evidence of when reconstruction began and ended;

(G) Valid evidence to support the applicant's claim for a vessel designation of catcher vessel or catcher/processor vessel;

(H) Valid evidence of ownership of the vessel being used as the basis for eligibility for a license (for USCG documented vessels, valid evidence must be the USCG Abstract of Title), or if eligibility is based on a fishing history that has been separated from a vessel, valid evidence of ownership of the fishing history being used as the basis of eligibility for a license; and

(I) Valid evidence of the LOA of the vessel to be deployed by the license if different than the vessel used as the basis for eligibility for a license.

(iv) *Other information required for special circumstances.*

(A) *Successor-in-interest.* If an applicant is applying as the successor-in-interest to an eligible applicant, an application, to be complete, also must contain valid evidence proving the applicant's status as a successor-in-interest to that eligible applicant and:

(1) Valid evidence of the death of that eligible applicant at the time of application, if the eligible applicant was or is an individual; or

(2) Valid evidence that the eligible applicant is no longer in existence at the time of application, if the eligible applicant is not an individual.

(B) *Norton Sound crab species license endorsement.* If an applicant is applying for a crab species license endorsement for Norton Sound and if the applicant is a person, an application, to be complete, must contain valid evidence that the applicant was a State of Alaska permit holder for the Norton Sound king crab summer fishery in 1993 or 1994. If the applicant is a corporation, an application, to be complete, must contain valid evidence that the corporation owned or had a lease for a vessel on June 17, 1995, that participated in the Norton Sound king crab summer fishery in 1993 or 1994.

(C) *Extended general qualification period.* If an applicant is applying for a license based on meeting the general qualification period requirements of paragraph (k)(4)(i)(A)(2) or (k)(4)(i)(B)(2)

of this section, the application, to be complete, must indicate which single endorsement area the applicant has selected for license. A license cannot be endorsed for more than one area, notwithstanding the fact that the applicant may have the documented harvests to qualify for more than one endorsement area.

(D) *Unavoidable circumstances.* If an applicant is applying for a license based on an unavoidable circumstance pursuant to paragraph (k)(8)(iv) of this section, an application, to be complete, must contain the information required by that paragraph and valid evidence of the date the vessel on which the application is based was lost, damaged, or otherwise unable to participate in the fishery, and the date a documented harvest was made from the replacement vessel.

(v) *Application evaluation.* The Regional Administrator will evaluate an application submitted during the specified application period and compare all claims in the application with the information in the official LLP record. Claims in the application that are consistent with information in the official LLP record will be accepted by the Regional Administrator. Inconsistent claims in the application, unless verified by evidence, will not be accepted. Pursuant to paragraph (k)(6)(vii) of this section, an applicant who submits inconsistent claims, or an applicant who fails to submit the information specified in paragraphs (k)(6)(iii) and (k)(6)(iv) of this section, will be provided a 60-day evidentiary period pursuant to paragraph (k)(6)(vii) of this section to submit the specified information, submit evidence to verify his or her inconsistent claims, or submit a revised application with claims consistent with information in the official LLP record. An applicant who submits claims that are inconsistent with information in the official LLP record has the burden of proving that the submitted claims are correct.

(vi) *Additional information or evidence.* The Regional Administrator will evaluate additional information or evidence to support an applicant's inconsistent claims submitted within the 60-day evidentiary period pursuant to paragraph (k)(6)(vii) of this section. If the Regional Administrator determines that the additional information or evidence meets the applicant's burden of proving that the inconsistent claims in his or her application is correct, the official LLP record will be amended and the information will be used in determining whether the applicant is eligible for a license. However, if the Regional Administrator determines that

the additional information or evidence does not meet the applicant's burden of proving that the inconsistent claims in his or her application is correct, the applicant will be notified by an initial administrative determination, pursuant to paragraph (k)(6)(viii) of this section, that the applicant did not meet the burden of proof to change the information in the official LLP record.

(vii) *60-day evidentiary period.* The Regional Administrator will specify by letter a 60-day evidentiary period during which an applicant may provide additional information or evidence to support the claims made in his or her application, or to submit a revised application with claims consistent with information in the official LLP record, if the Regional Administrator determines that the applicant did not meet the burden of proving that the information on the application is correct through evidence provided with the application. Also, an applicant who fails to submit information as specified in paragraphs (k)(6)(iii) and (k)(6)(iv) of this section will have 60 days to provide that information. An applicant will be limited to one 60-day evidentiary period. Additional information or evidence, or a revised application, received after the 60-day evidentiary period specified in the letter has expired will not be considered for purposes of the initial administrative determination.

(viii) *Initial administrative determinations (IAD).* The Regional will prepare and send an IAD to the applicant following the expiration of the 60-day evidentiary period if the Regional Administrator determines that the information or evidence provided by the applicant fails to support the applicant's claims and is insufficient to rebut the presumption that the official LLP record is correct, or if the additional information, evidence, or revised application is not provided within the time period specified in the letter that notifies the applicant of his or her 60-day evidentiary period. The IAD will indicate the deficiencies in the application, including any deficiencies with the information, the evidence submitted in support of the information, or the revised application. The IAD will also indicate which claims cannot be approved based on the available information or evidence. An applicant who receives an IAD may appeal pursuant to § 679.43. An applicant who avails himself or herself of the opportunity to appeal an IAD will not receive a transferable license until after the final resolution of that appeal, notwithstanding the eligibility of that applicant for some claims based on

consistent information in the application.

(ix) *Issuance of a non-transferable license.* The Regional Administrator will issue a non-transferable license to the applicant on issuance of an IAD if required by the license renewal provisions of 5 U.S.C. 558. A non-transferable license authorizes a person to deploy a vessel to conduct directed fishing for license limitation groundfish or crab species as specified on the non-transferable license, and will have the specific endorsements and designations based on the claims in his or her application. A non-transferable license will expire upon final agency action.

(7) *Transfer of a groundfish license or a crab species license—(i) General.* The Regional Administrator will transfer a groundfish license or a crab species license if a complete transfer application is submitted to Restricted Access Management, Alaska Region, NMFS, and if the transfer meets the eligibility criteria as specified in paragraph (k)(7)(ii) of this section. An application form may be requested from the Regional Administrator.

(ii) *Eligibility criteria for transfers.* A groundfish license or crab species license can be transferred if:

(A) The designated transferee is eligible to document a fishing vessel under Chapter 121, Title 46, U.S.C.;

(B) The parties to the transfer do not have any fines, civil penalties, other payments due and outstanding, or outstanding permit sanctions resulting from Federal fishing violations;

(C) The transfer will not cause the designated transferee to exceed the license caps in § 679.7(i); and

(D) The transfer does not violate any other provision specified in this part.

(iii) *Contents of application.* To be complete, an application for a groundfish license transfer or a crab species license transfer must be signed by the license holder and the designated transferee, or the individuals representing them, and contain the following, as applicable:

(A) Name, business address, telephone number, and FAX number of the license holder and the designated transferee;

(B) Name, state registration number (e.g., ADF&G number), and, if applicable, the USCG documentation number of the vessel to be deployed with the license (i.e., the designated vessel) after the transfer is approved;

(C) Valid evidence that the designated transferee is a person eligible to document a fishing vessel under Chapter 121, Title 46, U.S.C.;

(D) A legible copy of a contract or sales agreement that specifies the

license to be transferred, the license holder, the designated transferee, the monetary value or the terms of the license transfer, and the signature of the license holder and the designated transferee; and

(E) Information regarding whether a broker was used for the transaction, whether the license was collateralized, and other information the Regional Administrator deems necessary for measuring program performance.

(iv) *Incomplete applications.* The Regional Administrator will return an incomplete transfer application to the applicant and identify any deficiencies if the Regional Administrator determines that the application does not meet all the criteria identified in paragraph (k)(7) of this section.

(v) *Transfer by court order, operation of law, or as part of a security agreement.* The Regional Administrator will transfer a groundfish license or a crab species license based on a court order, operation of law, or a security agreement if the Regional Administrator determines that the transfer application is complete and the transfer will not violate any of the provisions of this section.

(vi) *Voluntary transfer limitation.* A groundfish license or a crab species license may be voluntarily transferred only once in any calendar year. A voluntary transfer is a transfer other than one pursuant to a court order, operation of law, or a security agreement. An application for transfer that would cause a person to exceed the transfer limit of this provision will not be approved.

(vii) *Request to change the designated vessel.* A request to change the vessel designated on an LLP groundfish or crab species license must be made on a transfer application. If this request is approved and made separately from a license transfer, it will count towards the annual limit on voluntary transfers specified in paragraph (k)(7)(vi) of this section.

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[FR Doc. 99-20206 Filed 8-5-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Food and Drug Administration

21 CFR Part 522

Implantation and Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to include a limitation in the approval of Pliva d.d.'s abbreviated new animal drug application (ANADA). The regulation did not state that use of Pliva d.d.'s oxytetracycline injection in cattle is limited to use in nonlactating dairy cattle. At this time, the regulation is amended to reflect the limitation.

EFFECTIVE DATE: August 6, 1999.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 30, 1999 (64 FR 23186), FDA published a document reflecting approval of Pliva d.d.'s ANADA 200-232 for use of Geomycin 200 (oxytetracycline injection) in cattle and swine. The amendment to the regulation did not state that the product is not for use in lactating dairy cattle. At this time, the regulations in 21 CFR 522.1660(d)(1)(iii) are amended to reflect the limitation in the approval.

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 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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