REVISIONS TO IFR ALTITUDES & CHANGEOVER POINTS—Continued

[Amendment 471, effective date December 20, 2007]

From	To	MEA
§ 95.6133 VOR Federal Airway V133 Is Amended To Read in Part		
Mansfield, OH VORTAC	Sandusky, OH VOR/DME	3000
Sandusky, OH VOR/DME	Gemini, OH FIX	*3000
*2000—MOCA		
Gemini, OH FIX	U.S. Canadian Border	*3400
*2300—MOCA		
U.S. Canadian Border	Detroit, MI VOR/DME	*3400
*2300—MOCA		
§ 95.6166 VOR Federal Airway V166 Is Amended To Read in Part		
Westminster, MD VORTAC	Belay, MD FIX	*3000
*2500—MOCA		
Belay, MD FIX	*Bains, MD FIX	2000
*7500—MRA		
Bains, MD FIX	Dupont, DE VORTAC	2000
§ 95.6220 VOR Federal Airway V220 Is Amended To Read in Part		
Kearney, NE VOR	Hastings, NE VOR/DME	4300
§ 95.6257 VOR Federal Airway V257 Is Amended To Read in Part		
Delta, UT VORTAC	*Verne, UT FIX	11500
*12200—MCA Verne, UT FIX, N BND		
Verne, UT FIX	*Staco, UT FIX	13000
*10500—MCA Staco, UT FIX, S BND		
Staco, UT FIX	Moint, UT FIX	*13000
*8900—MOCA		
Moint, UT FIX	*Krebs, UT FIX	**13000
*13000—MRA		
**9600—MOCA		
Krebs, UT FIX	Malad City, ID VOR/DME	*11000
*10000—MOCA		

From	To	MEA	MAA
§ 95.7001 Jet Routes **§ 95.7184 Jet Route J184 Is Amended To Read in Part**			
Buckeye, AZ VORTAC	Deming, NM VORTAC	23000	45000

[FR Doc. E7–23176 Filed 11–28–07; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 2006F–0409]

Secondary Direct Food Additives Permitted in Food for Human Consumption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to expand the conditions for the safe use of cetylpyridinium chloride (CPC) as an antimicrobial agent in a pre-chiller or post-chiller solution for application to raw poultry carcasses. This action is in response to a petition filed by Safe Foods Corp. (Safe Foods).

DATES: This rule is effective November 29, 2007. Submit written or electronic objections and requests for a hearing by December 31, 2007. See section VIII of the **SUPPLEMENTARY INFORMATION** of this document for information on the filing of objections. The Director of the Office of the **Federal Register** approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 173.375(a) as of November 29, 2007.

ADDRESSES: You may submit written or electronic objections and requests for a hearing, identified by Docket No. 2006F–0409, by any of the following methods:

Electronic submissions

Submit electronic objections in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written objections in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of objections, FDA is no longer accepting objections submitted to the agency by e-mail. FDA encourages you to continue to submit electronic objections by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All objections received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Raphael A. Davy, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1272.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of October 25, 2006 (71 FR 62475), FDA announced that a food additive petition (FAP 6A4767) had been filed by Safe Foods Corp., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 173.375 *Cetylpyridinium chloride* (21 CFR 173.375) to expand the conditions for the safe use of CPC as an antimicrobial agent applied in a pre-chiller or post-chiller solution to raw poultry carcasses.

CPC is currently approved under § 173.375 for use as an antimicrobial agent to treat the surface of raw poultry carcasses prior to immersion in a chiller when applied as a fine mist spray at a level not to exceed 0.3 grams CPC per pound of raw poultry carcass. As conditions of safe use, the solution must contain food grade propylene glycol (PG) at a concentration of 1.5 times that of the CPC, and the solution must be used in systems that collect and recycle solution that is not carried out of the system with the treated poultry carcasses.

Safe Foods initially petitioned for the use of a solution containing up to 1 percent CPC and PG at a level 1.5 times that of CPC as a liquid aqueous stream for either pre- or post-chiller application without a limit on the amount of CPC applied per carcass. When application of the CPC solution is not followed by immersion in a chiller, the treatment would be followed by a potable water rinse of the carcass. Safe Foods subsequently amended their petition by decreasing the maximum concentration of CPC in the treatment solution from 1 percent to 0.8 percent. As discussed in section II of this document, to mitigate concerns associated with residual PG in the treated poultry becoming a component of animal feed, in particular cat food, Safe Foods also proposed a maximum limit of 5 gallons of solution per carcass and a minimum of 99 percent recovery of the applied solution.[1]

II. Determination of Safety

Under the general safety standard in section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define ''safe'' as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

To establish with reasonable certainty that a food additive is not harmful under its intended conditions of use, FDA considers the projected human dietary intake of the additive, existing toxicological data, and other relevant information (such as published literature) available to the agency. FDA compares an individual's estimated daily intake (EDI) of the additive from all food sources to an acceptable intake level established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all sources of the additive. The agency commonly uses the EDI for the 90th percentile consumer of a food additive as a measure of high chronic dietary intake.

At a maximum CPC application concentration of 0.8 percent and assuming the worst-case maximum application volume of 5 gallons of solution per carcass, FDA estimates that the mean EDI of CPC from the petitioned use is 27.5 micrograms per person per day (µg/p/d) and the intake at the 90th percentile is 65 µg/p/d (Ref. 1). These EDIs subsume the exposure from the currently regulated use. As part of FDA's safety evaluation, the agency reviewed data submitted with the petition from two sub-chronic (90-day) toxicity studies on CPC fed to rats and dogs. FDA concluded that the no-observable-effect level (NOEL) for the dog, which was the most sensitive species tested, is 8.00 milligrams per kilogram body-weight per day (mg/kg-bw/day). By applying a 1,000-fold safety factor to this NOEL, the agency calculated the acceptable daily intake (ADI) for CPC for a 60 kilogram human as 0.48 mg/p/d. Therefore, taking into account the available safety information and the conservative estimates of intake of CPC, the agency concludes that the proposed use of CPC to treat raw poultry carcasses is safe for humans (Ref. 2).

FDA also considered the safety of the proposed use of PG, which is used in the CPC solution to maintain the solubility and stability of the solution and reduce absorption of CPC on the treated poultry. PG is generally recognized as safe as an ingredient in human food for multiple uses and as a processing aid provided that it is used in accordance with good manufacturing practices (21 CFR 184.1666). The agency does not have any safety concerns regarding the proposed use of PG in the CPC solution for treating poultry for human consumption. Because it is common for poultry and poultry byproducts to be used in animal feed, including cat food, the agency considered potential animal exposure from the petitioned use of the CPC solution. As part of the agency's evaluation of the first CPC petition that established § 173.375 (FAP 2A4736), FDA considered the safety of CPC-treated poultry and poultry byproducts used in animal feed. Because PG is toxic to cats, the substance is prohibited from use in cat food unless the use has been authorized by FDA through the issuance of a regulation providing for its safe use as a food additive (21 CFR 589.1001). FDA has previously stated in its rulemaking declaring PG for use in cat food not generally recognized as safe that PG levels at or below 0.02 percent (200 parts per million (ppm)) in cat food is safe (61 FR 19542, May 2, 1996). To

[1]While typical application volumes would be on the order of 0.5 gallon per carcass, the 5 gallon maximum limit is to account for infrequent occasions during processing when the line speed may temporarily be slowed down or stopped (e.g., to accommodate inspection of the processing line by U.S. Department of Agriculture (USDA) personnel).

mitigate any potential concerns associated with the possibility of residual PG becoming a component of cat food, should it become authorized as a food additive for such use, the petitioner has proposed a maximum limit of 5 gallons of solution per carcass and a minimum of 99 percent recovery of the applied solution. FDA concludes that potential PG residues in cat food from CPC solution containing a maximum level of 0.8 percent CPC, applied at a maximum volume of 5.0 gallons of solution per carcass, and a minimum of 99 percent of the applied CPC solution captured and recovered will ensure that the 200 ppm PG limit will not be exceeded (Ref. 3).

III. Updating of Specifications for CPC

The agency is updating § 173.375 by citing the specifications for CPC in the 30th edition of the United States Pharmacopeia/National Formulary (USP 30/NF 25) that are incorporated by reference rather than the 24th edition (USP 24/NF 19). We compared the specifications for CPC in the 24th and 30th editions of the USP and found them to be identical. Therefore, the agency is making this editorial change.

IV. Comments

The agency received several comments in response to the notice announcing the filing of the petition. One comment expressed concern that some microorganisms washed free from the treated carcasses will continue to thrive in the recovered solution and could potentially contaminate poultry as the solution is reused.

The agency agrees that microbes washed off the treated carcasses may be present in the recovered solution. However, the agency believes that the growth of these organisms will be controlled by CPC present in the recovered solution. Furthermore, as part of good manufacturing practices, the user of the CPC solution for treating poultry is expected to take appropriate steps to maintain an application solution of acceptable microbiological quality, including sampling and analysis of the solution to ascertain the microbiological quality of the treatment solution and to determine when the solution in the treatment tank needs to be changed.

In response to this comment, it should be noted that the trials that were conducted with recycled spray solution showed that aerobic plate counts (APC) from the carcasses treated with recycled spray solution were extremely low compared to those from the untreated carcasses. If bacteria were continuing to thrive in the recycled solution, the APC from the treated carcasses would have increased. However, this was not the case. For these reasons, FDA has no concerns about contamination of poultry from the recycled solution.

One comment concerned an efficacy trial conducted by the petitioner in which carcasses were tested post-chiller and after neutralizing CPC on the treated carcasses with activated carbon. The comment expressed concern that bacteria may have been trapped by the activated carbon producing a ''false negative'' result for the treated carcasses. However, the petitioner has stated that all 2,300 samples in the trial were ''neutralized'' with activated carbon whether or not the sample was treated with the CPC solution. The *Salmonella* incidence for the samples not treated with the CPC solution ranged from 20–22 percent positive, while the *Salmonella* incidence was only 4 percent positive for the CPC-treated samples. If the activated carbon was ''trapping'' the bacteria, the incidence levels in the untreated and treated samples would be expected to be more similar. That is, the fact that the positive incidence rate was significantly lower in the treated samples than in the untreated samples shows the effectiveness of the CPC treatment, not the trapping of the bacteria, which would be expected to occur to a similar extent in both CPC-treated and untreated carcasses. Thus, the available data confirm that the results from this efficacy study were not adversely affected by the use of activated carbon to neutralize CPC on the samples.

One comment was from a user of the product who claims that when CPC was used in their plant for the currently-regulated use, they received customer complaints about discoloration of their poultry product. Data from the petitioner showed that CPC does not provide a lasting technical effect and that its use would not result in any organoleptic changes to treated poultry. Furthermore, this customer experienced problems with discoloration of products that were not treated with a CPC solution. Therefore, it is unlikely that CPC was causing the discoloration. In addition, the petitioner stated that CPC solution is being used in similar applications in seven other poultry plants without any complaints of discoloration that can be attributed to CPC. Therefore, FDA does not believe that CPC used in accordance with the conditions in the regulation will cause discoloration of the treated poultry.

One comment expressed concern with potential occupational hazards posed by CPC and concentration of CPC in wastewater effluent, specifically: (1) Over complaints from inspectors for the USDA Food Safety and Inspection Service (FSIS) about the impact of other approved antimicrobial agents on the health of meat and poultry plant employees, and about increased respiratory problems from introduction of antimicrobials into the production process; (2) that the Material Safety Data Sheet (MSDS) identified physical hazards if CPC is not used properly (i.e., irritation to the skin, eye, respiratory and digestive systems); and (3) that CPC is a synthetic enzyme that does not break down easily and will accumulate in recycled water systems used by poultry processing facilities.

The agency's response to the first two concerns is that the USDA's New Technology Staff is responsible for reviewing new technologies that companies employ to ensure that their use is consistent with agency regulations and will not adversely affect product safety, inspection procedures, or the safety of FSIS inspectors. USDA is not aware of any health-related complaints from inspection personnel regarding the use of CPC in federally-inspected poultry plants. Furthermore, complaints or potential health issues associated with the use of one particular antimicrobial agent (e.g., tri-sodium phosphate) are not necessarily applicable to every other antimicrobial agent used for the same purpose. The physical hazards listed on the MSDS for CPC (i.e., severe skin irritation, severe eye irritation, severe irritation to the respiratory system, harmful if swallowed, may cause severe irritation to the digestive system) are physical hazards listed on MSDSs for numerous chemical compounds that are used routinely and safely everyday throughout the United States both in industry and by consumers. The physical hazards that are listed on an MSDS inform the user of the potential damaging effects to tissues and organs associated with direct exposure to the compound and remind the user of that substance of precautions that should be taken to avoid these adverse effects. Furthermore, as noted by the petitioner, the CPC solution is applied in a specially designed and fully automated cabinet, which limits worker exposure.

In response to the comment that CPC is a synthetic enzyme that does not degrade easily, first, the agency notes that CPC is not classified as an enzyme; it is a quaternary ammonium compound. Second, data provided in the environmental assessment for FAP 2A4736 demonstrated that any CPC that enters poultry facility water systems will quickly bind to organic solids suspended in the water and will not

remain solubilized in the water. To support this fact, the petitioner provided results of an experiment in which a solution containing 22.3 ppm CPC was added to publicly owned treatment works sludge material. In less than 1 minute, CPC was not detectable at a sensitivity of approximately 10 parts per billion (ppb) in the water with the treated sludge. Based on the data submitted in that environmental assessment, it was concluded that CPC would be present in poultry plant wastewater at levels below 0.01 ppb. Therefore, the available data do not indicate a potential for CPC to accumulate in recycled poultry plant water systems.

One comment expressed concern that the petitioner: (1) Did not provide adequate data that demonstrate the expanded use of CPC meets the requirements of a secondary direct food additive; (2) did not provide sufficient data such as a material balance that accounts for the CPC that is applied; and (3) did not provide sufficient requirements (flow rate, spray pressure, time, temperature, and spray distance) for the potable water rinse requirements following CPC application. The comment also suggested that the regulation provide details on the recovery system depending on line speed.

The agency notes that, regarding CPC's ongoing technical effect, the petitioner presented data in FAP 6A4767 to demonstrate that the food additive does not have an ongoing technical effect in poultry treated with the CPC solution. Because the technical effect of CPC on treated poultry occurs during processing but not after processing, it is considered a processing aid. Therefore, FDA has determined that it is appropriate to regulate the petitioned use of CPC as a secondary direct food additive rather than as a direct food additive.

FDA disagrees with the comment about insufficient data to account for the CPC that may enter the environment from use of the additive. Information submitted in the environmental assessment for this petition, which included mass balance information, was used by FDA to estimate environmental introductions from the proposed use of the additive. Based on this information, FDA estimated that environmental concentrations of CPC will be in the low ppb level. The comment contains no information that would cause the agency to change its conclusion that there will be no significant impact to the environment resulting from the petitioned use of the additive.

Regarding the comment about insufficient details for ensuring an adequate potable water rinse of CPC-treated poultry, FDA believes that it is sufficient for such requirements to be provided by each company that markets CPC to each poultry processor that uses the product. Because of plant-to-plant variation in processing conditions and equipment, a single set of specific parameters for the potable water rinse would not be appropriate in all processing facilities.

The petitioner further noted that testing described in the current petition indicates that the CPC residues remaining on the treated poultry carcass are not significantly affected by the duration or volume of the water rinse. Thus, the comment appears to overstate the effect of these variables on the efficiency of CPC removal and its potential introduction to the environment. As is clear from the agency's review of the data in FAP 2A4736 and in the current petition, the residual levels of CPC in treated carcasses are minimal and do not raise a health or safety concern.

Regarding the suggestion of including the details of the recovery system in the regulation, FDA strongly disagrees with this comment. FDA has determined that the petitioned use of the CPC solution containing a maximum level of 0.8 percent CPC, applied at a maximum volume of 5.0 gallons of solution per carcass, and a 99 percent recovery of the applied solution is safe. FDA does not believe it is necessary to include details of recovery system design in order to meet these conditions of safe use. Therefore, the agency concludes that it would be overly prescriptive to have such equipment requirements in a food additive regulation.

V. Conclusion

FDA reviewed data in the petition and other available relevant material to evaluate the safety of the use of CPC as an antimicrobial agent in a solution applied to raw poultry carcasses either pre- or post-chiller. Based on this information, the agency concludes that the proposed use of the additive is safe. Therefore, the conditions of use listed in § 173.375 should be amended as set forth in this document.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition will be made available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which the objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition

date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from Folmer, Chemistry Review Group, Division of Petition Review, to Davy, Division of Petition Review, July 10, 2007.

2. Memorandum from Khan, Toxicology Review Group, Division of Petition Review, to Davy, Division of Petition Review, July 25, 2007.

3. Memorandum from Benjamin, Animal Feed Safety Team, Division of Animal Feeds, to Davy, Division of Petition Review, July 18, 2007.

List of Subjects in 21 CFR Part 173

Food additives, Incorporation by reference.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN COUNSUMPTION

■ 1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Revise § 173.375 to read as follows:

§ 173.375 Cetylpyridinium chloride.

Cetylpyridinium chloride (CAS Reg. No. 123–03–05) may be safely used in food in accordance with the following conditions:

(a) The additive meets the specifications of the United States Pharmacopeia (USP)/National Formulary (NF) described in USP 30/NF 25, May 1, 2007, pp. 1700–1701, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Pkwy., Rockville, MD 20852, or you may examine a copy at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

(b) The additive is used in food as an antimicrobial agent as defined in § 170.3(o)(2) of this chapter to treat the surface of raw poultry carcasses. The solution in which the additive is used to treat raw poultry carcasses shall also contain propylene glycol (CAS Reg. No. 57–55–6) complying with § 184.1666 of this chapter, at a concentration of 1.5 times that of cetylpyridinium chloride.

(c) The additive is used as follows:

(1) As a fine mist spray of an ambient temperature aqueous solution applied to raw poultry carcasses prior to immersion in a chiller, at a level not to exceed 0.3 gram cetylpyridinium chloride per pound of raw poultry carcass, provided that the additive is used in systems that collect and recycle solution that is not carried out of the system with the treated poultry carcasses; or

(2) As a liquid aqueous solution applied to raw poultry carcasses either prior to or after chilling at an amount not to exceed 5 gallons of solution per carcass, provided that the additive is used in systems that recapture at least 99 percent of the solution that is applied to the poultry carcasses. The concentration of cetylpyridinium chloride in the solution applied to the carcasses shall not exceed 0.8 percent by weight. When application of the additive is not followed by immersion in a chiller, the treatment will be followed by a potable water rinse of the carcass.

Dated: November 12, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7–23182 Filed 11–28–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Part 62

[Public Notice: 5998]

Exchange Visitor Programs—Sanctions and Terminations

AGENCY: Department of State.

ACTION: Final rule; withdrawal.

SUMMARY: On November 2, 2007, the State Department published in the **Federal Register** a final rule entitled Exchange Visitor Programs—Sanctions and Terminations. The Department amended its regulations to add to and modify the existing actions for which the Department may sanction a sponsor. The change in the regulations will streamline the review process to offer sanctioned sponsors the procedural due process rights equal to those that the Administrative Procedure Act guarantees. In addition, the Rule eliminated summary suspension and modifies program suspension to halt the activities of a sponsor that has committed a serious act of omission or commission which has or could have the effect of endangering the health, safety, or welfare of an exchange visitor, or damage the national security interests of the United States. This rule is being withdrawn because it was submitted to OMB for formal significance designation; however, it was published prior to that determination being made. Since OMB's designation was that it is significant and they would like to formally review it, OMB has requested the rule to be withdrawn in its entirety.

DATES: The final rule published at 72 FR 62112, November 2, 2007, is withdrawn effective November 29, 2007.

FOR FURTHER INFORMATION CONTACT: Stanley S. Colvin, Director, Office of Exchange Coordination and Designation, U.S. Department of State, SA–44, 301 4th Street, SW., Room 734, Washington, DC 20547, (202) 203–7415; or e-mail at *jexchanges@state.gov.*

SUPPLEMENTARY INFORMATION:

Background

On November 2, 2007, the State Department published a final rule (Amendment No. 212 (72 FR 62112)). The rule, to have become effective December 3, 2007, was intended to revise its regulations presently set forth at 22 CFR part 62 subpart D (Sanctions) and 22 CFR part 62 subpart E (Termination and Revocation of Programs). The rule, to have become effective December 3, 2007, was intended to modify the reasons for which sanctions may be imposed and provide for program termination in the case of failure to file an annual management audit, in program categories requiring such audits. The rule would also provide for termination or denial of redesignation for an entire class of designated programs, if the Department determines that they compromise the national security of the United States, or no longer further the public diplomacy mission of the Department.

Reason for Withdrawal

This rule was submitted to OMB for formal significance designation; however, it was published prior to that determination being made. Since OMB's designation was that it is significant and