the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 1, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.447 is amended as follows:

i. By adding a heading to paragraph (a), designating the text following the heading as paragraph (a)(1), and alphabetically adding commodities to the table in newly designated paragraph (a)(1);

ii. By redesignating paragraphs (b) and (c) as paragraphs (a)(2) and (a)(3);

iii. By adding and reserving new paragraphs (b) and (c); and

iv. By adding a heading to paragraph (d).

The additions read as follows:

§ 180.447 Imazethapyr, ammonium salt; tolerance for residues.

(a) *General.* (1) * * *

Commodity	Parts per million	Expiration/ Revocation Date
* * *	* *	* *
Rice, bran	2.5	1/1/03
Rice, grain	0.30	1/1/03
Rice, hulls	1.5	1/1/03
Rice, straw	0.20	1/1/03
* * *	* *	* *

* * * * *

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* * * *

[FR Doc. 01–6329 Filed 3–13–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301103; FRL–6766–6]

RIN 2070–AB78

Pyriproxyfen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of the insecticide, pyriproxyfen [2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine] in or on all food items in food handling establishments where food and food products are held, processed and/or prepared at 0.1 ppm. McLaughlin Gormley King Company requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective March 14, 2001. Objections and requests for hearings, identified by docket control number OPP–301103, must be received by EPA on or before May 14, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301103 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph Tavano, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6411; and e-mail address: tavano.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected

categories and entities may include, but are not limited to:

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*.You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'', ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr http://www.access.gpo.gov/nara/cfr/cfrhtml—00/Title—40/40tab—00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301103. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of February 29, 2000 (65 FR 16608) (FRL–6493–8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) for tolerance by McLaughlin Gormley king Company, 8810 Tenth Avenue North, Minneapolis, MN 55427–4372. This notice included a summary of the petition prepared by McLaughlin Gormley King Company, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.510 be amended by establishing a tolerance for residues of the insecticide, Pyriproxyfen, [2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine], in or on food commodities at 0.5 part per million (ppm).

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of pyriproxyfen on all food items in food handling establishments where food and food products are held, processedand/or prepared at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by pyriproxyfen are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rodents	NOAEL = 23.49 mg/kg/day in males and 27.68 mg/kg/day in females LOAEL = 117.79 mg/kg/day in males and 141.28 mg/kg/day in females based on higher mean total cholesterol and phospholipids, decreased mean RBCs, hematocrit and hemoglobin counts and increased relative liver weight.
870.3150	90-Day oral toxicity in dogs	NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on increased absolute and relative liver weight in males and hepatocellular hypertrophy in females. These findings were also observed at 1000 mg/kg/day and may represent adaptive changes at both 300 mg/kg/day and the limit dose of 1000 mg/kg/day .
870.3200	21-Day dermal toxicity in rats	NOAEL = >1,000 mg/kg/day for systemic effects limit dose. LOAEL = for systemic effects was not established in this study. No dermal or systemic toxicity at the limit dose.
870.3700a	Prenatal developmental in rats	Maternal NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on increased incidences in mortality and clinical signs at 1,000 mg/kg/day with decreases in food consumption, body weight, and body weight gain together with increases in water consumption at 300 and 1,000 mg/kg/day . Developmental NOAEL = 300 mg/kg/day LOAEL = 1,000 mg/kg/day based on increased incidences of skeletal variations and unspecified visceral variations at 1,000 mg/kg/day.
870.3700b	Prenatal developmental in rabbits	Maternal NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on based on premature delivery/abortions, soft stools, emaciation, decreased activity and bradypnea. Developmental NOAEL = 300 mg/kg/day LOAEL: only 4 litters examined at 1,000 mg/kg/day [HDT] without effects.
870.3800	Reproduction and fertility effects	Parental/Systemic NOAEL = 1,000 mg/kg/day LOAEL = 5,000 mg/kg/day based on based on decreased body weight, weight gain and food consumption in both sexes and both generations. Increased liver weight in both sexes of the F1 generation and liver and kidney histopathology in F1 males. Reproductive NOAEL = 5,000 ppm [HDT]. Offspring NOAEL = 1,000 ppm. LOAEL = 5,000 ppm based on decreased pup body weight on lactation days 14 and 21.
870.4100	Chronic toxicity dogs	NOAEL = 100 mg/kg/day LOAEL = 300 mg/kg/day based on based on decreased weight gain, increased absolute and relative liver weight, mild anemia, increased cholesterol and triglycerides in both sexes and slight anemia in males.
870.4200	Carcinogenicity mice	NOAEL = 600 ppm
870.4300	2-Year Chronic Feeding/ Oncogenicity rats	LOAEL = 3,000 ppm based on renal lesions in both sexes. No statistically significant increase in tumor incidence relative to controls were observed in either sex at any dose up to 3,000 ppm [HDT]. NOAEL = 35.1 mg/kg/day for females and >138 mg/kg/day for males. LOAEL = 182.7 mg/kg/day for females based on decrease of 16.9% in body weight gain at 3,000 ppm. No evidence of carcinogenic response.
870.5100 and 870.5265	Gene Mutation Assay(Ames Test)/Reverse Mutation	Negative for induction of gene mutation measured as the reversion to histidine protrophy of 5 *S. typhimurium* strains and *E. Coli* WP2 uvra at doses from 10 to 5,000 μg/plate with and without S-9 activation. The highest dose was insoluble.
870.5300	Gene Mutation Assay Mammalian Cells	Negative for mutagenicity in Chinese hamster V79 cells with and without metabolic activation up to cytotoxic doses [300 μg/mL].
870.5380	Structural Chromosomal Aberration Assay *In vivo* cytogenetics	Nonclastogenic in Chinese hamster ovary cells both with and without S-9 activation up to cytotoxic doses [300 μg/mL].

TABLE 1.— SUBCHRONIC, CHRONIC, AND OTHER TOXICITY—Continued

Guideline No.	Study Type	Results
870.5550	Other Genotoxicity Assays (Unscheduled DNA Synthesis in HeLa cells)	Did not induce an increase in unscheduled DNA synthesis both with and without activation in HeLa cells exposed up to insoluble doses ranging to 6.4 μg/mL [without activation] and 51.2 μg/mL [with activation].
870.7485	Metabolism	Rats were orally dosed with ^{14}C-labeled pyriproxyfen at 2 or 1,000 mg/kg and at repeated oral doses [14 daily doses] of unlabeled pyriproxyfen at 2 mg/kg followed by administration of a single oral dose of labeled pyriproxyfen at 2 mg/kg. Most radioactivity was excreted in the feces [81–92%] and urine [5–12%] over a 7 day collection period. Expired air was not detected. Tissue radioactivity levels were very low [less than 0.3%] except for fat. Examination of urine, feces, liver, kidney, bile and blood metabolites yielded numerous > 20 identified metabolites when compared to synthetic standards. The major biotransformation reactions of pyriproxyfen include: 1. Oxidation of the 4' - position of the terminal phenyl group; 2. Oxidation at the 5' - position of pyridine; 3. Cleavage of the ether linkage and conjugation of the resultant phenols with sulfuric acid.

B. Toxicological Endpoints

The NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for pyriproxyfen used for human risk assessment is shown in the following Table 2:

TABLE 2.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRIPROXYFEN FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary general population including infants and children	Not Applicable	Not Applicable	There were no effects that could be attributed to a single exposure (dose) in oral toxicity studies including the developmental toxicity studies in rats and rabbits.
Chronic Dietary all populations	NOAEL = 35.1 mg/kg/day; UF = 100; Chronic RfD = 0.35 mg/kg/day	FQPA SF = 1; cPAD = 0.35/1 = 0.35 mg/kg/day	Combined/chronic toxicity - rat: LOAEL = 182.7 mg/kg/day based on decreased weight gain in female rats.
Long-Term Dermal (several months to lifetime) (Residential)	NOAEL= 35.1 mg/kg/day	LOC for MOE = 100	Combined/chronic toxicity - rat: LOAEL = 182.7 mg/kg/day based on decreased weight gain in female rats.
Long-Term Inhalation (several months to lifetime) (Residential)	NOAEL= 35.1 mg/kg/day	LOC for MOE = 100	Combined/chronic toxicity - rat: LOAEL = 182.7 mg/kg/day based on decreased weight gain in female rats.

TABLE 2.— SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR PYRIPROXYFEN FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	''Group E'' human carcinogen	Not Applicable	There is no evidence of carcinogenic potential. Therefore, a cancer risk assessment is not required.

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.510 (a) for the residues of pyriproxyfen, in or on the following raw agricultural commodities: pome fruits (crop group 11) (0.2 ppm), citrus fruits (crop group 10) (0.3 ppm), fruiting vegetables (except cucurbits) (crop group 8) (0.2 ppm), tree nuts (crop group 14) (0.02 ppm), cotton seed (0.05 ppm), cotton gin byproducts (2.0 ppm), almond hulls (2.0 ppm), citrus oil (20 ppm), and citrus pulp, dried (2.0 ppm). In todays action tolerances will be established for the residues of pyriproxyfen in or on all foods at 0.10 ppm as a result of the proposed use of pyriproxyfen in food handling establishments. Risk assessments were conducted by EPA to assess dietary exposures from pyriproxyfen in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. An acute dose and endpoint was not selected for any population subgroup for pyriproxyfen. No effects that could be attributed to a single exposure (dose) were observed in oral toxicity studies including the developmental toxicity studies in rats and rabbits. A dose and endpoint were not identified for acute dietary risk assessment; therefore, the Agency concludes that there is a reasonable certainty of no harm from acute dietary exposure.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. A conservative analysis was conducted using published and recommended tolerance level residues and 100% crop treated assumptions for all commodities. No anticipated residues or percent crop treated estimates were used. The residue levels of all food commodities, except those with existing tolerances, were set at 0.1 ppm. For commodities with tolerances greater than 0.1 ppm, existing tolerance level residues were employed. The cPAD for all population subgroups is 0.35 mg/kg/day. For chronic dietary risk estimates, HED's level of concern is for exposures >100% cPAD. Dietary exposure estimates for the U.S. population and other representative subgroups are presented in the following table 3:

TABLE 3.—SUMMARY OF RESULTS FROM CHRONIC DEEM ANALYSIS OF PYRIPROXYFEN

Subgroups	Exposure (mg/kg/day)	%cPAD
U.S. Population (48 states)	0.003258	0.9
All infants (< 1 year)	0.005538	1.6
Children (1–6 years)	0.008956	2.6
Children (7–12 years)	0.005229	1.5
Females 13–50 yrs	0.002323	0.7
Males 13–19 yrs	0.003158	0.9
Males 20+ yrs	0.002228	0.6
Seniors 55+	0.002233	0.6

The population subgroups listed include those subgroups having sufficient numbers of survey respondents in the CSFII food consumption survey to be considered statistically reliable. The results show that chronic dietary exposure to pyriproxyfen residues from all existing and proposed uses do not exceed HED's level of concern of 100% cPAD. Refinement of residue estimates using %CT corrections and anticipated residue estimates would result in even lower residue estimates.

2. *Dietary exposure from drinking water.* The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to pyriproxyfen they are further discussed in the aggregate risk sections below.

Based on the PRZM/EXAMS and SCI-GROW models the estimated environmental concentrations (EECs) of pyriproxyfen for acute exposures are estimated to be 0.11 parts per billion (ppb) for surface water and 0.006 ppb for ground water. The EECs for chronic exposures are estimated to be 0.11 ppb for surface water and 0.006 ppb for ground water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Pyriproxyfen is currently registered for use in residential non-dietary sites for flea and tick control. Formulations include contact sprays, emulsifiable concentrates, and impregnated materials (pet collars). With the exception of the pet collar uses, consumer use of pyriproxyfen typically results in short-term, intermittent exposures. Hence, chronic residential post-application exposure and risk assessments were conducted to estimate the potential risks from pet collar uses. The risk assessment was conducted using the following assumptions: application rate of 0.58 mg ai/day (product label), average body weight for a 1 to 6 year old child of 10 kg, the active ingredient dissipates uniformly through 365 days (the label instructs to change the collar once a year), and 1% of the active ingredient is available for dermal and inhalation exposure per day (assumption from Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments, 18-DEC-1997). The assessment also assumes an absorption rate of 100%. This is a conservative assumption since the dermal absorption was estimated to be 10% (HED Hazard Identification Assessment Review Committee, 24-OCT-1997). The following Table 4 shows residential exposure and risk Assessment for homeowner use of pet collars:

TABLE 4.—RESIDENTIAL EXPOSURE AND RISK ASSESSMENT FOR HOMEOWNER USE OF PET COLLARS

Population Subgroup	Application Rate[1] mg/day	Average Potential Dose Rate[2] (mg/kg/day)	Chronic Term MOE[3]
Children	0.58	0.00058	61,000
Adults	0.58	0.000081	430,000

[1]Product label: Reg. No. 2382-149 (0.5% pyriproxyfen, ovisterilant pet collar). Application rate = 42 gm collar × 0.5% a.i./collar × 1,000 mg/1 gm × 1/365 days. Collar to be replaced once a year.

[2]Potential Dose Rate (PDR) = Application rate × fraction of ai available for exposure (1%) × absorption rate(100%) × 1/(10 or 71.8 kg bw for children or adults, respectively) (Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments, 18-DEC-1997).

[3]Dermal and Inhalation NOAEL = 35.1 mg/kg/day; MOE = NOAEL/Exposure; Adequate MOE = 100.

The estimated chronic term MOE is 61,000 for children, and 430,000 for adults. The risk estimates indicate that potential risks from pet collar uses do not exceed HED's level of concern (MOEs < 100).

4. *Cumulative exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA does not have, at this time, available data to determine whether pyriproxyfen has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, pyriproxyfen does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pyriproxyfen has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children*—i. *In general.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity.* The oral perinatal and prenatal data demonstrated no indication of increased sensitivity of rats or rabbits to *in utero* and postnatal exposure to pyriproxyfen.

iii. *Conclusion.* The 10X safety factor to protect infants and children was reduced to 1x because (1) the toxicology data base is complete; (2) there is no indication of increased susceptibility of rats or rabbit fetuses to *in utero* and/or postnatal exposure in the developmental and reproductive toxicity studies; (3) a developmental neurotoxicity study is not required; (4) food exposure estimates are unrefined (assuming tolerance level residues and 100% CT) and likely result in an overestimate of the actual dietary exposure; (5) EFED models are used for ground and surface source drinking water exposure assessments resulting in conservative estimates of actual dietary exposures; and (6) the Draft Standard Operating Procedures for Residential Exposure Assessments have been used as the basis for all calculations which normally rely on one or more upper-percentile assumptions and are considered to be protective.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is

available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, OPP concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. An acute dietary dose and endpoint was not identified. Thus the risk from acute aggregate exposure is considered to be negligible.

2. *Chronic risk*. Using the conservative exposure assumptions described above, EPA has calculated that the maximum percentage of the cPAD that will be utilized by dietary (food) exposure to residues of pyriproxyfen is 2.6% percent for children (1–6 years). Chronic residential exposure to pyriproxyfen from pet collars is estimated to increase total pyriproxyfen exposure to infants and children only marginally. Despite the potential for exposure to pyriproxyfen in drinking water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

EPA bases this determination on a comparison of estimated concentrations of pyriproxyfen in surface and ground water to calculated drinking water levels of comparison. The estimates of pyriproxyfen in surface and ground water are derived from water quality models that use conservative assumptions regarding the pesticide transport from the point of application to surface and ground water. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with the pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impact of pyriproxyfen in food and drinking water as part of the aggregate chronic risk assessment process.

The following table 5 summarizes the quantitative aspects of the aggregate risk assessment for chronic exposure to pyriproxyfen. For chronic exposure to pyriproxyfen in surface and ground water, the DWLOCs are 12,000 µg/L for U.S. population and 3,400 µg/L for children (1–6 years). Estimated average concentrations of pyriproxyfen in surface and ground water are 0.11 ppb and 0.006 ppb, respectively. The estimated average concentrations of pyriproxyfen in surface and ground water are less than EPA's level of concern for pyriproxyfen in drinking water as a contribution to chronic aggregate exposure. Therefore, taking into account present uses and uses proposed in this action, EPA concludes that there is a reasonable certainty that no harm will result to any population subgroup from chronic aggregate exposure to pyriproxyfen residues.

TABLE 5.—AGGREGATE RISK ASSESSMENT FOR CHRONIC EXPOSURE TO PYRIPROXYFEN

Population Subgroup	cPAD mg/kg/day	Exposure mg/kg/day	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population - all seasons	0.35	0.003258	0.11	0.006	12000
All Infants (<1 year)	0.35	0.005538	0.11	0.006	3400
Children (1–6 years)	0.35	0.008956	0.11	0.006	3,400
Children (7–12 years)	0.35	0.005229	0.11	0.006	3,400
Females (13–50 years)	0.35	0.002323	0.11	0.006	10,000
Males (13–19 years)	0.35	0.003158	0.11	0.006	12,000
Males (20+ years)	0.35	0.002228	0.11	0.006	12,000
Seniors (55+)	0.35	0.002233	0.11	0.006	12,000

3. *Short-term risk*. Pyriproxyfen is not expected to pose a short-term risk due to the lack of significant toxicological effects observed.

4. *Intermediate-term risk*. Pyriproxyfen is not expected to pose an intermediate-term risk due to the lack of significant toxicological effects observed.

5. *Aggregate cancer risk for U.S. population*. Pyriproxyfen is classified as Category E: not carcinogenic in two acceptable animal studies and is, therefore, not expected to pose a cancer risk to humans.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to pyriproxyfen residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Previously, the Agency successfully validated gas chromatography (GC) methods for pyriproxyfen on cotton seed and on pome fruits, citrus fruits, fruiting vegetables, and tree nuts. Biological Test Center (BTC) conducted an Independent Laboratory Validation (ILV) of the proposed enforcement method for tolerances of pyriproxyfen on four representative foods using high performance liquid chromatography (HPLC) with ultraviolet (UV) detection. Sugar, flour, lettuce and butter were selected to represent high sugar content foods, dry foods, high water content foods, and fatty foods, respectively. The limit of quantitation (LOQ) was 0.1 ppm for all foods except butter, which was 0.5 ppm. Sugar, flour, and lettuce samples were fortified at 0.1 and 0.5 ppm. Average recoveries ranged from 89% to 97% for these food samples. Butter was fortified at 0.5 and 2.4 ppm and gave an average recovery of 68%. Some modifications to the analytical method were necessary for the butter samples. With incorporation of these modifications, EPA considers the ILV of the pyriproxyfen (Nylar®) analytical method for food commodities to be successful.

Agency validation of the HPLC method on flour, candy, lettuce, and butter, and of the GC method on liver was requested and completed. EPA concludes these methods are adequate as analytical enforcement methods pending revision of the methods as requested by the Agency laboratory.

Valent submitted data from a study performed by Corning Hazleton Inc. describing the testing of pyriproxyfen through the Food and Drug Administration (FDA) Multiresidue Methods Protocols A, C, D, E, and F found in the Pesticide Analytical Manual Volume I (PAM I), Appendix II. This study was previously reviewed in a memo dated 06-MAY-1997. Pyriproxyfen was recovered from fortified apple and cotton samples through protocols A, C, D, E, and F. The metabolite PYPAC was tested with protocols A, B, C, and D. The multiresidue methods will serve as confirmatory methods for residues of pyriproxyfen. The multiresidue recovery data were sent to the FDA for inclusion in PAM I.

The methods may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

There are no CODEX, Canadian, or Mexican tolerances for pyriproxyfen residues in or on any food items or raw agricultural commodities (RACs). Maximum residue limits (MRLs) have been proposed for cotton seed, citrus, meat, and edible offal; however, there is no certainty these proposed levels will become official. Therefore, international harmonization is not an issue at this time.

C. Conditions

As a condition of the registration a revised analytical method for foods must be submitted.

V. Conclusion

Therefore, a tolerance is established for residues of pyriproxyfen [2-[1-methyl-2-(4-phenoxyphenoxy)ethoxy]pyridine], in or on all foods at 0.10 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301103 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before May 14, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301103, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.''

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 28, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.510(a) is amended by designating the text following the heading ''General'' as paragraph (a)(1), and by adding paragraph (a)(2) to read as follows:

§ 180.510 Pyriproxyfen; tolerances for residues.

(a) *General.* (1) * * *

(2) A tolerance of 0.10 parts per million is established for all foods as a result of the proposed use of NYLAR in food handling establishments where food and food products are held, prepared, processed or served. Application is limited to space, general surface, spot, and/or crack and crevice treatment in food handling establishments where food and food products are held, processed, prepared and served. Space and general surface application may be used only when the facility is not in operation provided exposed food is covered or removed from the area being treated prior to application. Spot, and/or crack and crevice treatment may be used while the facility is in operation provided exposed food is covered or removed from the area being treated prior to application. Food contact surfaces should be thoroughly washed with an effective cleaning compound and rinced with potable water after use of the product. To assure safe use of this additive, its label and labeling shall conform to that registered with the U.S. Environmental Protection Agency, and shall be used in accordance with such label and labeling.

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[FR Doc. 01–6330 Filed 3–13–01; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 410, 414, 424, 480, and 498

[HCFA–3002–CN]

RIN 0938–AI96

Medicare Program; Expanded Coverage for Outpatient Diabetes Self-Management Training and Diabetes Outcome Measurements

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule; correction and confirmation of effective date.

SUMMARY: In the December 29, 2000 issue of the **Federal Register** (65 FR 83130), we published a final rule that implements section 4105 of the Balanced Budget Act by expanding Medicare coverage for outpatient diabetes self-management training and establishes outcome measurements for evaluating the improvement of the health status of Medicare beneficiaries with diabetes. The final rule provided for a 60-day delay from the publication date in implementing the expanded coverage of the diabetes training; that is, February 27, 2001. We unknowingly delayed forwarding our report on the final rule to the Congress for review under 5 U.S.C. 801(a) at the time we published the final rule. This document reaffirms that the final rule, and its expansion of Medicare coverage for outpatient diabetes self-management training, went into effect on February 27, 2001, notwithstanding the delay in forwarding our report to the Congress. It also corrects cost assumptions that were overstated in the final rule.

DATES: The effective date of the final rule published December 29, 2000 (65 FR 83130), is confirmed as February 27, 2001.

FOR FURTHER INFORMATION CONTACT: Mary Stojak, (410) 786–6939.

SUPPLEMENTARY INFORMATION: In the December 29, 2000 issue of the **Federal Register** (65 FR 83130), we published a final rule that implements section 4105 of the Balanced Budget Act by expanding Medicare coverage for outpatient diabetes self-management training and establishes outcome measurements for evaluating the improvement of the health status of Medicare beneficiaries with diabetes. Under the congressional review provisions of 5 U.S.C. Chapter 8, the Administrator of the Office of Management and Budget's Office of Information and Regulatory Affairs determined that the final rule was a ''major rule'' as defined in 5 U.S.C. 804(2). In accordance with 5 U.S.C. 801(a)(3), we provided a 60-day delay period for the final rule's effective date, so that the final rule was effective on February 27, 2001.

We recently learned that we inadvertently overlooked forwarding our report to the Congress under 5 U.S.C. 801(a) at the time of the final rule's publication. The Congress subsequently received our report on February 13, 2001. Therefore, under 5 U.S.C. 801(a)(3), the general consequence of this delay would be that the effective date would no longer be February 27, 2001, but instead would be April 14, 2001, which is 60 days after the Congress received our report.

Under 5 U.S.C. 808(2), however, we find, for good cause, that a second, additional 60-day delay in the final rule's effective date would be contrary to the public interest. There has already been one 60-day effective-date delay period. As we have noted, our failure to submit the report to Congress on a timely basis was an inadvertent administrative oversight. We have reviewed and reinforced our administrative procedures to ensure that this does not occur again. An additional 60-day delay in the effective date would directly harm Medicare beneficiaries with diabetes who are eligible for the self-management training. Under the terms of the final rule, Medicare coverage for persons with diabetes was expanded on February 27, 2001. An additional 60-day delay in the effective date would therefore delay this expansion in coverage and preclude eligible beneficiaries with diabetes from receiving needed training for another 60 days. Medicare beneficiaries who have diabetes and are eligible for training should not be disadvantaged as a result of an administrative oversight. All interested parties have supported this expansion of Medicare coverage for beneficiaries with diabetes. Moreover, while the final rule was determined at its issuance to be a ''major'' economic rule (and thus subject to the 60-day minimum effective date), our actuaries have recently reviewed the impact analysis again. Based on this recent review, our actuaries believe that some of their cost assumptions overstated the likely costs of the rule. In particular, the actuaries believe that their previous analysis overstated the likely level of utilization by beneficiaries of the new benefit. The current estimate by our actuaries is that the final rule does not reach the $100 million threshold for a major economic rule. Indeed, it will have an annual impact of less than $100 million in any one year ($45 million in FY2001, $90 million in FY2002, $80 million in FY2003, $95 million in FY2004, and $95 million in FY2005).

The Office of Management and Budget (OMB) stated in its March 30, 1999 government-wide guidance to agencies on the Congressional Review Act (OMB Memorandum M–99–13), that use of the waiver authority in section 808(2) could be considered, on a case-by-case basis, in the case of final rules for which the rulemaking agency had previously requested public comment (as occurred in this case). Based on the OMB Memorandum, and for the reasons we have outlined above, we find that delaying the effective date for this major final rule for another 60 days would be contrary to the public interest, and therefore, find that there is good cause for invoking Section 808(2) and retaining the final rule's original effective date of February 27, 2001. In arriving at this decision, we have consulted with OMB, which concurs with this conclusion.