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).

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: December 18, 2000.

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 180.516 is amended by alphabetically adding commodities to the table in paragraph (a) to read as follows:

§ 180.516 Fludioxonil; tolerances for residues.

(a) *General.* A tolerance is established for residue of the fungicide fludioxonil, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1*H*-pyrrole-3-carbonitrile) in or on the following food commodities:

Commodity	Parts per million
* * * * *	
Grape	1.0
* * * * *	
Onion, dry bulb	0.20
Onion, green	7.0
* * * * *	
Strawberry	2.0
* * * * *	

* * * * *

[FR Doc. 00–33168 Filed 12–28–00; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301098; FRL–6762–7]

RIN 2070–AB78

Extension of Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends time-limited tolerances for the pesticides listed in Unit II of this document. These actions are in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of these pesticides. Section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA.

DATES: This regulation is effective December 29, 2000. Objections and requests for hearings, identified by docket control number OPP–301098, must be received by EPA on or before February 27, 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 III. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301098 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: See the listing below for the name of a specific contact person. The following information applies to all contact persons: Emergency Response Team, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9366.

Pesticide/CFR cite	Contact person
2,4-D (§ 180.142)	Beth Edwards
Paraquat (§ 180.205)	Libby Pemberton
Lambda-cyhalothrin (§ 180.438).	Andrew Ertman
Bifenthrin and difenoconazole (§ 180.442 and § 180.475, respectively).	Andrea Conrath
Fenbuconazole (§ 180.480).	Dan Rosenblatt
Sulfentrazone and imazamox (§ 180.498 and § 180.508, respectively).	Barbara Madden

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/.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–301098. 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

EPA has previously issued a final rule for each chemical/commodity which were published in the **Federal Register** on the date listed in the summary for each chemical/commodity listed below. The initial issuance of these final rules announced that EPA, on its own initiative, under 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) was establishing time-limited tolerances. EPA established the tolerances because section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Such tolerances can be established without providing notice or time for public comment.

EPA received requests to extend the use of these chemicals for this year's growing season. After having reviewed these submissions, EPA concurs that emergency conditions exist. EPA assessed the potential risks presented by residues for each chemical/commodity. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. The data and other relevant material have been evaluated and discussed in the final rule originally published to support these uses. Based on that data and information considered, the Agency reaffirms that extension of these time-limited tolerances will continue to meet the requirements of section 408(l)(6). Therefore, the time-limited tolerances are extended until the date listed below. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations (CFR). Although these tolerances will expire and are revoked on the date listed, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on the commodity after that date will not be unlawful, provided the residue is present as a result of an application or use of a pesticide at a time and in a manner that was lawful under FIFRA, the tolerance was in place at the time of the application, and the residue does not exceed the level that was authorized by the tolerance. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Tolerances for the use of the following pesticide chemicals on specific commodities are being extended:

1. *2,4-D*. EPA has authorized under FIFRA section 18 the use of 2,4-D on wild rice for control of common water plantain in Minnesota. This regulation extends a time-limited tolerance for residues of the herbicide 2,4-dichlorophenoxyacetic acid in or on wild rice at 0.1 ppm for an additional 2–year period. This tolerance will expire and is revoked on December 31, 2002. A time-limited tolerance was originally published in the **Federal Register** on September 5, 1997 (62 FR 46900) (FRL–5738–9).

2. *Paraquat*. EPA has authorized under FIFRA section 18 the use of paraquat on artichokes for control of weeds in California. This regulation extends a time-limited tolerance for residues of the herbicide paraquat in or on artichokes at 0.05 ppm for an additional 2–year period. This tolerance will expire and is revoked on December 31, 2002. A time-limited tolerance was originally published in the **Federal Register** on November 22, 1999 (64 FR 63714) FRL–6392–9).

3. *Lambda-cyhalothrin*. EPA has authorized under FIFRA section 18 the use of lambda-cyhalothrin on barley for control of Russian wheat aphid in Wyoming, Montana, Idaho, and Colorado and sugarcane for the control of the sugarcane borer in Louisiana. This regulation extends time-limited tolerances for combined residues of the insecticide lambda-cyhalothrin and its epimer in or on barley, bran at 0.2 ppm; barley, grain at 0.05 ppm; barley, hay at 2.0 ppm; barley, straw at 2.0 ppm, and sugarcane at 0.03 ppm for an additional 2–year period. These tolerances will expire and are revoked on December 31, 2002. Time-limited tolerances were originally published in the **Federal Register** on January 29, 1999 (64 FR 4584–4590) (FRL–6056–2).

4. *Bifenthrin*. EPA has authorized under FIFRA section 18 the use of bifenthrin on citrus for control of Diaprepes root weevil in Florida. This regulation extends time-limited tolerances for residues of the insecticide bifenthrin in or on citrus, whole fruit; citrus, oil; and, citrus, dried pulp at 0.05, 0.3, and 0.3 ppm, respectively, for an additional 2–year period. These tolerances will expire and are revoked on December 31, 2002. Time-limited tolerances were originally published in the **Federal Register** on December 16, 1998 (63 FR 69200) (FRL–6048–1).

5. *Difenoconazole*. EPA has authorized under FIFRA section 18 the use of difenoconazole on sweet corn grown for seed for control of fungal pathogens in Florida. This regulation extends time-limited tolerances for residues of the fungicide difenoconazole in or on Corn, sweet (kernel + corn with husk removed); Corn, sweet, forage; and Corn, sweet, stover at 0.1 ppm for an additional 2–year period. These tolerances will expire and are revoked on 12/31/02. Time-limited tolerances were originally published in the **Federal Register** on September 1, 1999 (64 FR 47680) (FRL–6094–3).

6. *Fenbuconazole*. EPA has authorized under FIFRA section 18 the use of fenbuconazole on blueberries for control of mummy berry disease in Georgia. This regulation extends a time-limited tolerance for combined residues of the fungicide fenbuconazole alpha-2-(4-chlorophenyl)-ethyl-alpha-phenyl-3-(1*H*-1,2,4-triazole)-1-propanenitrile and its metabolites cis-5-(4-chlorophenyl)-dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl)-2-3*H*-furanone and trans-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazole-1-ylmethyl-2-3H-furanone expressed as fenbuconazole in or on blueberries at 1.0 ppm for an additional 2–year period. This tolerance will expire and is revoked on December 31,

2002. A time-limited tolerance was originally published in the **Federal Register** on June 10, 1998 (63 FR 31633) (FRL–5791–5).

7. *Sulfentrazone*. EPA has authorized under FIFRA section 18 the use of sulfentrazone on cowpea and lima bean for control of hophornbeam copperleaf in Tennessee and on sunflower for control of weeds in North Dakota. This regulation extends a time-limited tolerance for residues of the herbicide sulfentrazone, *N*-[2,4-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-y-l]phenyl] methanesulfonamide in or on bean, succulent seed without pod (lima beans and cowpeas) and sunflower at 0.1 ppm for an additional 2–year period. These tolerances will expire and are revoked on December 31, 2002. A time-limited tolerance was originally published in the **Federal Register** on September 21, 1999 (64 FR 51060) (FRL–6097–8).

8. *Imazamox*. EPA has authorized under FIFRA section 18 the use of imazamox on canola for control of wild mustard in Minnesota and North Dakota. This regulation extends a time-limited tolerance for residues of the herbicide imazamox, 2-4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1*H*-imidazol-2-yl-5-methoxymethyl-3-pyridine-carboxylic acid, applied as the free acid or ammonium salt in or on canola at 0.05 ppm for an additional 17–month period. This tolerance will expire and is revoked on December 31, 2003. A time-limited tolerance was originally published in the **Federal Register** on July 14, 1999 (64 FR 37855) (FRL–6086–5).

III. 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–301098 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 February 27, 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 issues(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 III.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–301098, 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 file format 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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

IV. Regulatory Assessment Requirements

This final rule establishes time-limited tolerances under FFDCA section 408. 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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 under FFDCA section 408(l)(6) in response to an exemption under FIFRA section 18, such as the tolerances 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).

V. 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: December 22, 2000.

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.

§ 180.142 [Amended]

2. In § 180.142, in the table to paragraph (b), amend the entry for ''Wild rice'' by revising the expiration date ''12/31/00'' to read ''12/31/02''.

§ 180.205 [Amended]

3. In § 180.205, in the table to paragraph (b), amend the entry for ''Artichokes'' by revising the expiration date ''12/31/00'' to read ''12/31/02''.

§ 180.438 [Amended]

4. In § 180.438, in the table to paragraph (b) amend the entries for ''Barley, bran''; ''Barley, grain''; ''Barley, hay''; ''Barley straw''; and ''Sugarcane'' by revising the expiration date ''12/31/00'' to read ''12/31/02''.

§ 180.442 [Amended]

5. In § 180.442, in the table to pararaph (b) amend the entries for ''Citrus, whole fruit''; ''Citrus oil''; and ''Citrus, dried pulp'' by revising the expiration dates ''12/31/00'' to read ''12/31/02''.

6. In § 180.475, revise the table in paragraph (b) to read as follows:

§ 180.475 Difenoconazole; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/ Revocation date
Corn, sweet (kernel + corn with husk removed)	0.1	12/31/02
Corn, sweet, forage	0.1	12/31/02
Corn, sweet, stover	0.1	12/31/02

* * * * *

§ 180.480 [Amended]

7. In § 180.480, in the table to paragraph (b) amend the entry for ''Blueberries'' by revising the expiration date ''12/31/00'' to read ''12/31/02''.

§ 180.498 [Amended]

8. In § 180.498, in the table to paragraph (b) amend the entries for ''Bean, succulent seed without pod (lima beans and cowpeas)'' and

''Sunflower'' by revising the expiration date ''12/30/00'' to read ''12/31/02''.

§ 180.508 [Amended]

9. In § 180.508, in the table to paragraph (b) amend the entry for ''Canola'' by revising the expiration date ''7/15/01'' to read ''12/31/03''.

FR Doc. 00–33292 Filed 12–27–00; 1:00 pm

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration Centers for Disease Control and Prevention

42 CFR Part 493

[HCFA–2024–FC2]

RIN 0938–AI94

Medicare, Medicaid, and CLIA Programs; Extension of Certain Effective Dates for Clinical Laboratory Requirements Under CLIA

AGENCY: Centers for Disease Control and Prevention (CDC) and Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule extends certain effective dates for clinical laboratory requirements in regulations published on February 28, 1992, that implemented provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This rule extends the phase-in date of the quality control requirements applicable to moderate and high complexity tests and extends the date by which an individual with a doctoral degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing.

These effective dates are extended to allow the Department to revise quality control requirements and establish the qualification requirements necessary for individuals with doctoral degrees to serve as directors of laboratories performing high complexity testing. These effective date extensions do not reduce the current requirements for quality test performance.

DATES: *Effective Date:* December 29, 2000.

Comment Date: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 27, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following addresses:

Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–2024–FC2, P.O. Box 8018, Baltimore, MD 21244–8018; and

Centers for Disease Control and Prevention, Department of Health and Human Services, Attention: HCFA–2024–FC2, 4770 Buford Hwy., N.E., MS F11, Atlanta, Georgia 30341–3724.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–8018.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–2024–FC2. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's office at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 to 5 p.m. (phone: (202) 690–7890). For information on ordering copies of the **Federal Register** containing this document and on electronic access, see the beginning of **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Rhonda S. Whalen (CDC), (770) 488–8155, Cecelia Hinkel (HCFA), (410) 786–3531.

SUPPLEMENTARY INFORMATION:

Availability of Copies, and Electronic Access

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–7800 (or toll free at 1–888–293–6498) or by faxing to (202) 512–2250. The cost for each copy is $8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. Free public access is available on a Wide Area Information Server (WAIS) through the Internet and via asynchronous dial-in. Internet users can access the database by using the World Wide Web; the Superintendent of Documents home page address is http://www.access.gpo.gov/su_docs/, by using local WAIS client software, or by telnet to swais.access.gpo.gov, then log in as guest (no password required). Dial-in users should use communications software and modem to call (202) 512–1661; type swais, then log in as guest (no password required).

I. Background

On February 28, 1992, we published in the **Federal Register** (57 FR 7002) final regulations with an opportunity for public comment. These regulations set forth the requirements for laboratories that are subject to CLIA. These regulations established uniform requirements for all laboratories regardless of location, size, or type of testing performed. In developing the regulations, we included requirements that would ensure the quality of laboratory services and be in the best interest of the public health. We recognized that a rule of this scope required time for laboratories to understand and implement the new requirements. Therefore, certain requirements were phased-in and given prospective effective dates. We also planned to address the comments we received on the February 28, 1992 rule and make modifications, if necessary, in the subsequent final rule.

On December 6, 1994, May 12, 1997, and October 14, 1998, we published in the **Federal Register** (59 FR 62606, 62 FR 25855, and 63 FR 55031, respectively) final rules with opportunity for comment. These rules extended the phase-in of the quality control requirements applicable to moderate and high complexity tests and the date by which an individual with a doctoral degree must possess board certification to qualify as a director of a laboratory that performs high complexity testing. These changes were made due to the resource constraints