2. The third sentence in section 4.1.2.1 which reads, in part, "* * * The second part would start when a defrost period is manually initiated * * *" is corrected to read "* * * The second part would start when a defrost period is initiated * * *".

3. In section 5.1.2, the reference in the last sentence in the section to section "* * * 4.1.3." is corrected to read "* * * 4.1.1."

Appendix B1 (Alternative) [Corrected]

1. Section 2.1 is corrected to replace the term "(32.±0.6°C)" with the term "(32.2±0.6°C)". Also, section 2.1 is to be placed in correct sequential position with regard to section 2.2.

2. Section 2.3 is corrected to delete the following sentence in its entirety: "[Note.—Change format of 2.3A to match format of 2.3B]". Also, paragraph A of section 2.3 which reads, in part, "* * * is compared to the average an equivalent time period * * *" is corrected to read "* * * is compared to the average over an equivalent time period * * *".

3. The third sentence in section 4.1.2.1 which reads, in part, "* * * The second part would start when a defrost period is manually initiated * * *" is corrected to read "* * * The second part would start when a defrost period is initiated * * *".

4. In section 5.1.2, the reference to the last sentence in the section to section "* * * 4.1.3." is corrected to read "* * * 4.1.1.".

5. The formula in section 5.2.1.1 which reads "ET=(EP × 1440 × k)/T" is corrected to read "ET=(EP × 1440 × K)/T".

6. The formula in section 5.2.1.2 which reads "ET=(1440 × EP1/T1) + ((EP2−(EP1 × T2/T1)) × K × 12/CT)" is corrected to read "ET=(1440 × K × EP1/T1) + ((EP2−(EP1 × T2/T1)) × K × 12/CT".

7. The formula in section 6.2.1.2 which reads "E=ET1 + ((ET2−ET1) × (0.0−TF1)/TF2−TF1)) is corrected to read "E=ET1 + ((ET2−ET1) × (0.0−TF1)/(TF2−TF1))".

[FR Doc. 83-7929 Filed 3-28-83; 8:45 a.m.]
BILLING CODE 6450-01-M

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

12 CFR Part 7

[Docket No. 83-14]

Interpretative Rulings

AGENCY: Comptroller of the Currency, Treasury.

ACTION: Final rule.

SUMMARY: This document contains a technical amendment which clarifies the Comptroller's interpretive ruling regarding a national bank's compliance with the five-year holding period for "salvage" real estate (12 CFR 7.3020).

EFFECTIVE DATE: March 29, 1983.

FOR FURTHER INFORMATION CONTACT: Nancy E. Chase, Attorney, Legal Advisory Services Division, Office of the Comptroller of the Currency, Washington, D.C. 20219, (202) 447-1880.

SUPPLEMENTARY INFORMATION: This amendment clarifies references to 12 U.S.C. 29 appearing in 12 CFR 7.3020(a)(1)-(2) and citing the statute's "second paragraph." Reference to the "second paragraph" is ambiguous since the statute contains both designated and undesignated paragraphs. Also, as has occurred in the past, amendment of the statute may change the number of a paragraph resulting in an incorrect paragraph reference in the regulation. In order to avoid these problems and to clarify which portion of the statute is being referenced in the regulation, this amendment refers to the substance of 12 U.S.C. 29 to which the regulation applies rather than to the applicable paragraph number of the statute.

This amendment to Interpretive Ruling 7.3020 (12 CFR 7.3020) is purely technical. It in no way affects a bank's obligation to comply or the permissible means of compliance with the provisions of 12 U.S.C. 29. For this reason, the Office finds, in accordance with 5 U.S.C. 553(b)(B), that notice and public comment are unnecessary.

Special Analyses

Since this amendment is not subject to notice and comment, preparation of a Regulatory Flexibility Analysis is not required. The Comptroller of the Currency believes, however, that the clarifications will facilitate the application of the existing regulation and will not have any particular effect on small entities.

The Office has determined that the amendment is not a "major rule" as defined by Executive Order 12291 and, therefore, a Regulatory Impact Analysis has not been prepared. The amendment will not have an annual effect on the economy of $100 million or more and will not result in a major increase in the cost of bank operations, government supervision of banks, or consumer services. The amendment also will not have adverse effects on competition, employment, investment, productivity or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

List of Subjects in 12 CFR Part 7

National banks, "Salvage" real estate.

Accordingly, 12 CFR Part 7 is amended to read as follows:

PART 7—INTERPRETIVE RULINGS

Subpart C—Bank Ownership of Property

1. The authority citation for Part 7 reads as follows:

Authority: R.S. 324 et seq., as amended; 12 U.S.C. 1 et seq., unless otherwise noted.

2. Section 7.3020 is amended by revising paragraphs (a)(1) and (a)(2) to read as follows:

§ 7.3020 Real estate acquired as salvage on uncollectable loans.

(a) *Disposal of "salvage" real estate within 5 years.*

(1) A national bank may comply with its obligation under 12 U.S.C. 29 to dispose within five years of real estate acquired by the bank for a debt previously contracted by retaining or transferring such real estate to a subsidiary or affiliate for use in the business of the bank, subsidiary or affiliate.

(2) Compliance with the requirement of 12 U.S.C. 29 that a bank dispose within five years of real estate acquired for a debt previously contracted may also be accomplished, subject to prior approval of the Regional Administrator of National Banks, by disposal of such real estate under an arrangement by which the bank will realize additional compensation upon the ultimate disposition of the property by the transferee where: (i) The bank has been unable to dispose of the real estate except at an unreasonably low price resulting in a substantial loss to the bank; and (ii) there is no reason to believe that a substantially higher price is obtainable for such real estate within a reasonable period.

* * * * *

Dated: March 14, 1983.

C. T. Conover,

Comptroller of the Currency.

[FR Doc. 83-8082 Filed 3-28-83; 8:45 am]
BILLING CODE 4810-33-M

FEDERAL HOME LOAN BANK BOARD

12 CFR Part 543

[No. 83-150]

Amendments Relating To Grandfathering of State Authority by Institutions Converting to Federal Charters

Dated: March 17, 1983.

AGENCY: Federal Home Loan Bank Board.

ACTION: Final rule.

SUMMARY: The Federal Home Loan Bank Board ("Board") is adopting a new regulation applicable to the grandfathering of rights enjoyed as state mutual savings banks by institutions converting to federal charter, whether those institutions retain their Federal Deposit Insurance Corporation ("FDIC") insurance coverage, or obtain insurance of accounts from the Federal Savings and Loan Insurance Corporation. Any converting institution will be allowed to retain its state mutual savings bank authority, and any federal association subsequently acquiring that converted institution by merger or consolidation will likewise be able to enjoy those grandfathered rights. Grandfathered rights may be transmitted through merger on an indefinite basis, as long as the disappearing institution had converted to a federal savings bank, and may not be defeated by the non-occurrence of a statutory condition precedent to their use at the time of conversion. This regulation is adopted to implement statutory changes made to § 5(i) of the Home Owners' Loan Act of 1933 by the Garn-St Germain Depository Institutions Act of 1982 ("Garn-St Germain Act").

EFFECTIVE DATE: March 17, 1983.

FOR FURTHER INFORMATION CONTACT: Peter M. Barnett, Associate General Counsel, Office of the General Counsel (202/377-6445) Federal Home Loan Bank Board, 1700 G Street, N.W., Washington, D.C. 20552.

SUPPLEMENTARY INFORMATION: The Financial Institutions Regulatory and Interest Rate Control Act of 1978, Pub. L. 95-630, amended section 5(a) of the Home Owners' Loan Act of 1933 ("HOLA") (12 U.S.C. 1464(a)) to authorize the Board, on a limited basis, to grant federal mutual savings bank charters. These charters were available only to institutions converting from the state mutual savings bank ("MSB") form. Because state-chartered MSBs often had powers exceeding those allowable to federal associations under the HOLA, the amendments to section 5(a) contained authorization for limited "grandfathering" of state authority. A federal MSB was permitted to carry on any activities it was engaged in on December 31, 1977, and to retain or make any investment of a type it held on that date, except that its equity, corporate bond, and consumer loan investments could not exceed the average ratio of such investments to total assets for the five-year period immediately preceding the filing of its application for conversion. Regulations regarding section 5(a) grandfathering authority were issued August 22, 1980 (45 FR 56033), and may be found at 12 CFR 578.2 (1982).

As part of its substantial enhancement of the investment and other authority available to federal thrift institutions, the Garn-St Germain Depository Institutions Act of 1982, Pub. L. 97-320, ("Garn-St Germain Act"), substantially broadened the grandfathering possibilities available to federal associations which formerly were state MSBs. These rights are available whether the conversion to federal charter took place under old section 5(a) of the HOLA, or under new section 5(i) or 5(o). Under new section 5(i)(5)(A) of the HOLA, any activity (including branching) or investment available under state law at the time of conversion from a state MSB may continue to be made by that institution as a federal association, to the extent authorized by the Board. In addition, under new section 5(i)(5)(B), any federal association that merges with a federal savings bank enjoying grandfathered rights acquires whose rights itself and, provided it first converts to a federal savings bank, if it does not already enjoy that status, may pass them on in turn to a federal association that absorbs it.

The 1980 regulations clearly were inadequate to address the new authorization. The Board, therefore, by Resolution No. 82-790 (47 FR 56314; published on December 16, 1982), proposed a new regulation setting forth in detail its interpretation of the appropriate extent of the authority provided by section 5(i)(5). However, in order to allow processing of charter conversions pursuant to final regulations promulgated by the Board in companion Resolution No. 82-791 (47 FR 56985; published on December 22, 1982), applicants otherwise eligible for approval have been permitted to apply for granfathered rights consistent with the Board's proposed regulation, upon the condition that newly-chartered institutions so approved will be required to conform with the Board's final rule or other Board action in further consideration of this area.

Proposed § 543.11-1 set forth in paragraph (a) the general standard applicable to grandfathering. As proposed, a federal association that at one time was a state MSB could exercise as a federal association any authority it had under state law at the time it ceased to be a state MSB. Such grandfathered authority could be exercised, however, only to the degree permitted under state law, except to the extent that such authority may be enjoyed by federal associations not enjoying grandfathered rights. Thus, in a hypothetical situation where state law allowed up to 20 percent of an institution's assets to be invested in commercial loans, subject to a more restrictive single-borrower limit than that applicable under federal law, a converted federal association could make commercial loans up to the 10-percent-of-assets limit applicable to federal associations in accordance with the more liberal federal loans-to-one-borrower statute, and comply with the state law requirement only for commercial loans made in excess of the federal percentage-of-assets ceiling. In addition, explicit authorization was provided in paragraph (a) to allow converted institutions to contiune to follow state law and regulation regarding grandfathered authority, except as otherwise provided by the Board.

Proposed paragraph (b) dealt with the passing on of grandfathered rights through merger or consolidation. Any federal association that acquires, by merger or consolidation, a federal savings bank enjoying grandfathered rights also would acquire those grandfathered rights. Those rights could be transmitted and retransmitted indefinitely to other federal associations in the same manner, assuming the disappearing association was a federal savings bank at the time of the merger or consolidation.

Proposed paragraph (c) clarified that grandfathering does extend to authority under state law that may be exercised only in accordance with the occurrence of a condition precedent, such as the occurrence of a future date, or the attainment of a specified level of net worth. Thus, if a savings bank under state law were allowed to make particular investments as long as it has 10 percent net worth, it would be permitted to make those investments as a federal association, provided it meets that net-worth requirement. The fact that the condition precedent has not yet

occurred at the time of conversion would not defeat grandfathering.

Finally, proposed paragraph (d) clarified that grandfathering is not to be construed as a device for allowing institutions more liberal authority than is allowed under the most liberal construction of state or federal law. For instance, if a state allows 20 percent of assets to be invested in a particular category and the HOLA allows 10 percent, a converted institution may not, as a result of grandfathering, be allowed to invest 30 percent of its assets in that category. Such a construction would be an overly generous interpretation of the statute.

The Board has determined to adopt the regulation as proposed, with several modifications.

First, the phrase "To the extent authorized by the Board" has been deleted where it appeared in proposed paragraphs (a) and (b), and the phrase "as determined by the Board" has been deleted from the second sentence of proposed paragraph (a). This action was taken to avoid giving the impression that the agency, with respect to applications for conversions or mergers in which grandfathering is involved, would determine on a case-by-case basis to what extent state authority would be retained. This was not the Board's intent in proposing the regulation. The use in the proposal of the deleted language was designed merely to signal that the Board would not uncritically and irrevocably accept an institution's own assessment of state authority, but would remain the ultimate arbiter of what rights attach. The Board's authority to act in this role, however, is clear under its general regulatory power stemming from, among other sources, sections 5(a) and 5(o) of the Home Owners' Loan Act of 1933, as amended by the Garn-St Germain Act. In addition, the reservation of authority in this regard is explicitly provided in the regulation in the second and third sentences of paragraph (a). Accordingly, retention of the deleted language would be redundant and confusing. The Board also is deleting the phrase "as determined by the Board" from proposed paragraphs (c) and (d) for the similar reason that to do otherwise would be confusing and, given the Board's plenary regulatory powers, redundant.

Until experience demonstrates that there is a positive need to take a contrary approach, for reasons of safety or soundness or otherwise, the Board will allow unrestricted grandfathering of state law investment and activity authority by converting savings banks, and in connection with mergers of institutions possessing grandfathered rights. There is no indication in the legislative history of the Garn-St Germain Act that such an approach is inappropriate; indeed, the basic thrust of that legislation was to deregulate thrift institutions and make them more effective competitors. The approach adopted was basically urged by one commenter, and opposed by another. The issue is reviewed in more detail in the following discussion of comments.

The Board also has determined to amend proposed paragraph (b) to clarify the existence of grandfathering rights with regard to certain institutions that were federal savings banks but that converted to federal savings and loan associations or merged into federal savings and loan associations prior to the enactment of the Garn-St Germain Act. The regulations as amended now explicitly states that those transactions will be regarded as having the same impact on grandfathering as they would if had they occurred subsequent to enactment. Thus, a federal savings and loan association that, prior to enactment, converted to that status from a federal savings bank, or absorbed a federal savings bank by merger, would be entitled to exactly the same grandfathering rights as would be extended if the conversion or merger occured after the Act became law. The Board believes the essentially remedial thrust of the Garn-St Germain Act strongly supports this approach, which was urged by one commenter.

Comments

In all, the Board received eleven letters of comment on the proposed regulation. Five comments were from savings banks, four were from trade associations, one was from a savings and loan association and one was from a law firm. Five commenters favored the proposal without qualification, five favored it but had supplementary comments or suggestions, and one generally opposed it.

Issues Raised by Commenters

1. *Extent of Grandfathering.* One commenter raised the basic objection that the Board should not allow converted institutions to exercise all state law authority permissible under the Garn-St Germain Act without restrictions, but instead, using specific criteria, should decide on the basis of case-by-case determinations, as part of the merger or conversion application process, which state powers should be grandfathered. The Board has considered this suggestion very carefully, in light of its responsibilities, particularly with regard to maintenance of the safety and soundness of insured institutions. The Board is not persuaded, however, that the nature of the activities potentially to be grandfathered is such as to warrant the imposition of a burdensome case-by-case analysis requirement upon institutions seeking to convert or merge. The powers in question all result from statutes passed by state legislatures, which, under the dual system of financial institution regulation long sanctioned by Congress, have a keen interest in the safety and soundness of the depository institutions operating with state charters. There is certainly no basis for an assumption on the Board's part that these powers, which converting institutions must enumerate as part of their application process, are inherently suspect because they have their origins in state rather than federal law, or that their combination with other authority allowed under the Home Owners' Loan Act would automatically generate supervisory or other problems.

Although the commenter states that Congress intends grandfathering to be limited to traditional activities of banks and savings and loans rather than new categories of activities prohibited to federals, the Board finds no persuasive evidence in the statute or its legislative history to justify such a restriction. The statute, found at section 5(i) (5)(A)(ii) of the Home Owners' Loan Act of 1933, as amended (to be codified at 12 U.S.C. 1464(i)(5)(A)(ii)), speaks very broadly of permitting grandfathering of any investment or activity "not otherwise authorized under this section," and there is no suggestion in the legislative history that this language should be narrowed to impose a "traditional activities" test. *See* S. Rep. 536, 97th Cong., 2d Sess. 53 (1982).

In the Board's view, the proper approach is to permit broad grandfathering, as proposed, and to maintain a careful watch on the use of expanded powers through our examination process. The Board is provided with extensive supervisory tools for dealing with potentially unsafe or unsound practices and, of course, is free to engage in corrective rulemaking at any time should problems arise. At a time when the Board is struggling to reduce the regulatory burdens that have contributed to the serious financial problems of the thrift industry, it would be anomalous to engage in the case-by-case scrutiny urged without convincing evidence that problems are likely to result from implementation of the broad grandfathering strategy authorized by the new statute.

The Board believes that the potential benefits to be derived from blanket grandfathering, in terms of, for example, increased investment authority, improved chances (as a result of enhanced franchise value) to raise capital, and broadened ability to serve customers and the community, all strongly argue in favor of initially allowing unfettered use of the authority extended by Congress.

While the commenter appears to indicate that Congress intends the Board to use a case-by-case approach because of the statutory phrase "to the extent authorized by the Board," the Board finds nothing in the legislative history of section 5(i) (5) that supports this view. The Board, as indicated, has considered the matter and has determined not to restrict the exercise of the grandfathering authority provided under the statute. The Board believes that it is a reasonable and appropriate construction of section 5(i) (5), particularly in light of the broad regulatory grant of authority to the Board under sections 5(a) and 5(c), to determine that the appropriate extent of grandfathering for each eligible institution is the maximum specified in the statute.

2. *Securities Activities.* One commenter requested the Board to specifically prevent the grandfathering provision from authorizing federal savings banks to engage in securities activities that it claims are prohibited under federal law. In brief, the commenter indicated a strong belief that for the Board to permit thrift institutions to engage in securities-related activities would be contrary to federal policy, as embodied in the Garn-St Germain Act, as well as inherently unsafe and unsound. In addition, the commenter points to the legislative history of the Garn-St Germain Act as a source of Congressional intent that federal thrifts should not engage in securities activities. The Board is not persuaded that it should adopt the proposed restriction.

Section 5(i) (5), by its terms, quite clearly provides that if an investment or activity is allowed under state law, a converted savings bank may import it into the federal system and pass it on by merger. There is nothing in the legislative history of that provision that suggests a different interpretation. The commenter states that the legislative history of the Garn-St Germain Act evidences displeasure with a proposed Board service corporation regulation, since withdrawn, which would have allowed service corporations to engage in a wide variety of businesses on a pre-approved basis, including certain securities-related activities. We have examined this history and do not believe it should be read to indicate that the activities proposed in the regulation were prohibited from being brought into the federal system by grandfathering. The purpose of grandfathering is to carve an exception in the general scheme governing federal association investments and activities for certain classes of institutions. The Board believes that this will not just prove valuable to institutions, their customers, and their communities, but will prove as well to be a valuable means for regulators and Congress to evaluate on a limited basis, the impact of varying degrees of increased thrift authority. Using the states as laboratories had a very beneficial impact in the NOW account area, and could yield similarly positive results in other fields as well. The commenter has not provided, and the Board has been unable to find, any persuasive authority for the proposition that Congress was so hostile to the notion of thrift involvement in securities activities that a special exception should be carved out of the grandfathering regulation to prohibit such activities.

With respect to the Glass-Steagall argument, the Board has already determined in connection with applications that, consistent with that Act, federal associations may operate a subsidiary that engages in securities activities. It is also noted that the Federal Deposit Insurance Corporation has reached the conclusion that authorization of securities activities for the subsidiary of a Massachusetts-chartered mutual savings bank would not be in violation of the Glass-Steagall Act.

Concerning the assertion that securities activities are unsafe and unsound for financial institutions, the Board has examined this issue carefully in connection with the previously mentioned service corporation subsidiary application. Given effective Securities and Exchange Commission regulation and the Board's own careful supervision, there is no reason why this line of business should pose a particular threat with respect to safety or soundness. Properly regulated, it should allow for increased competition in the marketplace, and enhanced profitability for the parent association.

3. *Exercise of Powers as a Condition Precedent to Grandfathering.* One commenter urged that the Board should have a presumption against grandfathering of any powers not actually exercised under state law, if not a direct prohibition on the initiation of such new activities. This suggestion was advanced on the basis that it would not disadvantage a converting institution to refrain from doing that which it has not done in the past. Again, there is no hint in the legislative history of Congressional preference for such an approach. Indeed, under prior law governing grandfathering, 12 U.S.C. 1464(a) (1982), a restriction similar to that urged was in existence. Its repeal and replacement, by language clearly allowing converted institutions to continue to rely on state law authority relating to investments and activities, suggests a preference for the approach proposed. There is no justification for denying a converting savings bank the ability to exercise, as a federal association, state law investment or activities options not utilized for some reason as a state institution.

4. *Survival of Grandfathered Powers in Mergers.* One commenter suggested that the Board should define the circumstances under which grandfathered powers may be passed along in mergers. This was regarded as desirable in that a federal association could enlarge its authority by merging with another institution with grandfathered rights, and that grandfathered activities that would be benign in a converted institution might raise safety and soundness concerns in a larger association. The commenter was particularly disturbed that a large institution could acquire additional powers by merging with a small institution with grandfathered authority.

Again, there is no suggestion in the statutory language or its legislative history that Congress wished the Board to limit the transmission of grandfathered rights through merger. After considering the matter, the Board fails to see any reason at this time to cut back on the full complement of rights extended under the statute, either by general rulemaking or by case-by-case scrutiny. Furthermore, the Board sees no basis for imposing special restrictions based on the respective size of the merger participants. With regard to concerns that the regulation allows federals to increase their authority through mergers with institutions having grandfathered rights, this is regarded as the precise intent of the statute, which is unambiguously phrased to permit such an enhancement of authority. As indicated previously, the Board has extensive supervisory resources for use in correcting abuses, and will use them if problems develop.

5. *Explicit State Law Authorization as Pre-Condition to Grandfathering.* One commenter suggested that an activity

should not be considered to be authorized under state law unless it is explicitly permitted by a valid state statutory or regulatory provision. Without such a restriction, the commenter believed there would be no degree of certainty regarding the types of investments in activities that might be allowed through grandfathering. The Board considered the merits of such an approach and concluded that, on balance, requiring a linkage to explicit statutory or regulatory language would be unduly cumbersome. Requiring federal associations, for example, to rely on the *explicit* terms of the Home Owners' Loan Act or the regulations issued thereunder would be extremely confusing. An important degree of reliance is placed upon interpretations of the Board and the courts, particularly with regard to inherent and incidental powers, to fill in the interstices of the statutory and regulatory scheme. The states operate in a similar manner. In the Board's view, this is another area best handed through careful supervisory monitoring of grandfathered powers. If a pattern of actual or attempted overstepping of state law occurs, the Board will consider taking appropriate remedial action.

6. *Effect of Post-Conversion Passage of State Laws.* One commenter recommended that activities authorized under state law after an institution converts should not be grandfathered. Two others took the opposite view. The Board does not believe the statute permits a converted institution to take advantage of a state law enacted after the date of conversion, and the regulation reflects this belief. The regulation does allow, however, an institution to take advantage of state authority enacted prior to conversion but unavailable to the institution at the time of conversion because of a delayed effective date or a failure to meet some other condition precedent.

7. *Notice, Comment and Hearing Procedures.* One commenter indicated that the Board should make available notice, comment and hearing procedures to parties interested in the grandfathered rights of converting institutions. Conversions of savings banks formerly were subject to such procedures, unlike conversions of other institutions. The Board has gained experience with savings banks, however, and in addition, the Act made designation as a savings bank an option available to all thrifts. Accordingly, the Board determined to conform the savings bank conversion procedures to those governing other conversions to federal charters. Such conversions are treated basically as business decisions of the institution, which the Board does not think need be routinely subjected to elaborate approval procedures.

The Board believes that the benefits, in terms of enhanced competitiveness and the ability to provide more flexible service to customers, which were the primary objectives of the Garn-St Germain Act, strongly argue in favor of deregulation in this area, rather than imposition of the potentially time-consuming and expensive procedures sought. There is no more justification for a notice, comment and hearing procedure aimed at individual institutions seeking to use this new empowerment than for imposing such a procedural hurdle on federal associations seeking to use their new abilities to lease tangible personal property, make commercial loans, or accept demand deposits. This is not to indicate, however, that the chartering/grandfathering process will be inaccessible to public scrutiny. Names of applicants are available through the Board's Federal Home Loan Banks, and, of course, the provisions of state law are widely known. Any party believing an institution is operating or will operate in defiance of applicable authority is encouraged to bring such information to the attention of the Board's Office of Examination and Supervision.

Final Regulatory Flexibility Analysis

1. *Reasons, objective, and legal basis underlying the proposed rule.* These elements have been incorporated elsewhere into the supplementary information regarding the regulation.

2. *Small entities to which the proposed rule will apply.* The rule will apply only to FSLIC-insured or federally-chartered institutions. At present, institutions eligible to convert and obtain grandfathering rights exist in fewer than twenty states.

3. *Overlapping or conflicting federal rules.* There are no known federal rules that may duplicate, overlap, or conflict with the regulation.

4. *Alternatives to the rule.* The regulation will allow certain institutions converting to federal charters to retain attractive state investment and other authority, and for that authority to be passed to other federal associations through merger. Small associations will be able to enjoy this right to the same extent as large institutions, and the regulation will thus be beneficial to them, by providing more organizational, investment and other flexibility. In addition, smaller institutions could become more attractive merger partners as a result of the regulation, which would be of great importance to institutions in financial difficulty. There is no disproportionate negative effect on small institutions. Because the regulation authorizes use of what currently appears to be the most liberal grandfathering interpretation available under the statute, it would not be possible to modify the proposal to make it more lenient and thus increase the benefits available under it to small institutions. Restricting the benefits of the regulation to small institutions could conceivably result in a relative improvement for small institutions, but the Board sees no basis for such an approach under the circumstances. The language of Section 5(i) certainly does not point in that direction.

One commenter criticized the Board's Intitial Regulatory Flexibility Analysis as inadequate. The Board has carefully reviewed its approach in this matter and has determined it to be consistent with the Regulatory Flexibility Act. That Act is basically designed to make agencies consider adjusting the imposition of regulatory restrictions in a way, if possible, to reduce burdens on small entities. It certainly was not designed to require artificially restricting by regulation the statutory investment and activities options open to large financial institutions in order to favor their smaller competitors.

Regulatory Analysis

The elements of regulatory analysis for major proposed regulations required by Board Resolution No. 80-584 (September 11, 1980) have been incorporated into the supplementary information regarding the regulation.

Effective Date

Because there is a present need to allow thrift institutions greater flexibility in their investment, organizational and other decision-making, the Board has determined that the 30-day delay of effective date following publication of the regulations pursuant to 12 CFR 508.11 and 15 U.S.C. 533(d) is unnecessary.

List of Subjects in 12 CFR Part 543

Savings and loan associations.

Accordingly, the Board hereby amends Part 543, Subchapter C, Chapter V of Title 12, Code of Federal Regulations, as set forth below.

SUBCHAPTER C—FEDERAL SAVINGS AND LOAN SYSTEM

PART 543—[AMENDED]

Add a new § 543.11–1, as follows:

§ 543.11–1 Grandfathered authority.

(a) A Federal savings bank formerly chartered or designated as a mutual savings bank under state law may exercise any authority it was authorized to exercise as a mutual savings bank under state law at the time of its conversion from a state mutual savings bank to a Federal or other state charter. Except to the extent such authority may be exercised by Federal associations not enjoying grandfathered rights hereunder, such authority may be exercised only to the degree authorized under state law at the time of such conversion. Unless otherwise determined by the Board, an association, in the exercise of grandfathered authority, may continue to follow applicable state laws and regulations in effect at the time of such conversion.

(b) A Federal association that acquires, or has acquired, a Federal savings bank by merger or consolidation may itself exercise any grandfathered rights enjoyed by the disappearing institution, whether such rights were obtained directly through conversion or through merger or consolidation. The extent of the grandfathered rights of a Federal association that disappeared prior to the effective date of this section shall be determined exclusively pursuant to this section.

(c) This section shall not be construed to prevent the exercise by a Federal association enjoying grandfathered rights hereunder of authority that is available under the applicable state law only upon the occurrence of specific preconditions, such as the attainment of a particular future date or specified level of net worth, which have not occurred at the time of conversion from a state mutual savings bank, provided they occur thereafter.

(d) This section shall not be construed to permit the exercise of any particular authority on a more liberal basis than is allowable under the most liberal construction of either state or federal law or regulation.

(Sec. 5, 48 Stat. 132, as amended (12 U.S.C. 1464); Reorg. Plan No. 3 of 1947; 3 CFR 1943–1948 Comp., p. 1071)

By the Federal Home Loan Bank Board.

J. J. Finn,

Secretary.

[FR Doc. 83-8055 Filed 3-28-83; 8:45 am]

BILLING CODE 6720-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Director, Veterinary Medicine, et al.

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority on food-related matters to add new delegations to Bureau of Veterinary Medicine officials. The new delegations of authority will expedite the administrative handling of certain routine actions of that Bureau.

EFFECTIVE DATE: March 29, 1983.

FOR FURTHER INFORMATION CONTACT: Robert L. Miller, Office of Management and Operations (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4976.

SUPPLEMENTARY INFORMATION: In § 5.31(e) (21 CFR 5.31(e)) the introductory paragraph is designated as paragraph (1), and paragraph (2) is added delegating to the Director and Deputy Director of the Bureau of Veterinary Medicine the authority to issue 180-day tentative responses to citizen petitions on animal food and drug matters.

In § 5.61(b) (21 CFR 5.61(b)) the introductory paragraph is designated as paragraph (1), and paragraph (2) is added delegating to the Director and Deputy Director of the Bureau of Veterinary Medicine the portion of the authority that relates to approvals of the use of food additivies. In § 5.61(c) (21 CFR 5.61(c)) the introductory paragraph is designated as paragraph (1), and paragraph (2) is added delegating to the Director and Deputy Director of the Bureau of Veterinary Medicine and the Associate Director and Deputy Associate Director for Surveillance and Compliance and the Director and Deputy Director of the Division of Animal Feeds of that Bureau the portion of the authority that relates to food additives.

Further delegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

List of Subjects in 21 CFR Part 5

Authority delegations (government agencies), Organization and functions (government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. In § 5.31 by revising paragraph (e), to read as follows:

§ 5.31 Petitions under Part 10.

* * * * *

(e)(1) The Director and Deputy Director of the Bureau of Foods are authorized to issue 180-day tentative responses to citizen petitions on food matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Bureau.

(2) The Director and Deputy Director of the Bureau of Veterinary Medicine are authorized to issue 180-day tentative responses to citizen petitions on animal food and drug matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Bureau.

2. In § 5.61 by revising paragraphs (b) and (c), to read as follows:

§ 5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, and color additives.

* * * * *

(b)(1) The Director and Deputy Director of the Bureau of Foods are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 401, 409, and 706 of the act regarding the issuance of notices of temporary permits for foods varying from standards of identity under § 130.17 of this chapter; and approvals of the use of food additives under section 409(e) of the act, and color additives, other than those on the provisional list, under section 706(d) of the act, where these approvals do not involve novel or controversial issues, including any question about the applicability of the Delaney Anti-Cancer Clause.

(2) The Director and Deputy Director of the Bureau of Veterinary Medicine are authorized to perform all of the functions of the Commissioner of Food and Drugs regarding approvals of the use of food additives under section 409(e) of the act, where these approvals do not involve novel or controversial issues, including any question about the

applicability of the Delaney Anti-Cancer Clause.

(c)(1) The Director and Deputy Director of the Bureau of Foods, and the Associate Director for Compliance and the Director and Deputy Director of the Division of Food and Color Additives of that Bureau are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act or to color additive petitioners under section 706(d)(1) of the act that relate to the assigned functions of that Bureau.

(2) The Director and Deputy Director of the Bureau of Veterinary Medicine, and the Associate Director and Deputy Associate Director for Surveillance and Compliance and the Director and Deputy Director of the Division of Animal Feeds of that Bureau are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act that relate to the assigned functions of that Bureau.

* * * * *

Effective date. This regulation shall become effective March 29, 1983.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: March 16, 1983.

Arthur Hull Hayes, Jr.,

Commissioner of Food and Drugs.

[FR Doc. 83-7936 Filed 3-28-83; 8:45 am]

BILLING CODE 4160-01-M

---

21 CFR Part 74

[Docket Nos. 82C-0396, 82C-0397, and 82C-0399]

D&C Green No. 6; Listing as a Color Additive For Use in Contact Lenses

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of D&C Green No. 6 as a color additive in contact lenses. The agency is taking this action in response to petitions filed by Baurs-Krey Associates, Inc., Syntex Ophthalmics, Inc., and Polymer Technology Corp.

DATES: Effective April 29, 1983; objections by April 28, 1983.

ADDRESS: Written objections may be sent to the Docket Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Garnett R. Higginbotham, Jr., Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690

SUPPLEMENTARY INFORMATION: In two notices published in the **Federal Register** of January 14, 1983 (48 FR 1822 and 1823), FDA announced that color additive petitions CAP 3C0171 (Docket No. 82C-0396) and CAP 3C0172 (Docket No. 82C-0397) had been filed by Baurs-Krey Associates, Inc., 630 Fifth Ave., New York, NY 10020, and Syntex Ophthalmics, Inc., P.O. Box 39600, Phoenix, AZ 85069, proposing that the color additive regulations be amended to provide for the safe use of D&C Green No. 6 as a color additive in contact lenses. In the **Federal Register** of January 28, 1983 (48 FR 4051), FDA announced that Polymer Technology Corp., 33 Industrial Way, Wilmington, MA 01887, had also petitioned (CAP 3C0164; Docket No. 82C-0399) the agency to approve the use of D&C Green No. 6 in contact lenses. The petitions were filed under section 706 of the Federal Food, and Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

I. The Color Additive

In the **Federal Register** of December 28, 1962 (27 FR 12828), FDA issued a final rule listng D&C Green No. 6 for coloring polyethylene terephthalate surgical sutures, including sutures for ophthalmic use (21 CFR 74.1206). FDA issued this regulation in response to color additive petition CAP 2C0004. In the **Federal Register** of April 25, 1975 (40 FR 18167), FDA amended § 74.1206 to provide for the use of D&C Green No. 6 in coloring polyglycolic acid surgical sutures, including sutures for ophthalmic use, as a result of a second petition (CAP 2C0104).

In the **Federal Register** of April 2, 1982 (47 FR 14138) FDA issued a final rule listing D&C Green No. 6 for use in externally applied drugs (21 CFR 74.1206) and cosmetics (21 CFR 74.2206). The preamble to the April 2, 1982 final rule provides a detailed account of the safety and regulatory history of D&C Green No. 6.

D&C Green No. 6 is principally 1,4-bis[(4-methylphenyl)amino]-9,10-anthracenedione (CAS Reg. No. 128-80-3). This material is formed by chemically reacting 1 molecule of quinizarin with 2 molecules of *p*-toluidine. Because no chemical reaction can be controlled to react all the starting materials and produce only the desired product, the resulting reaction mixture will contain some unreacted quinizarin and *p*-toluidine. This fact is significant because Weisburger, et al., have demonstrated that *p*-toluidine is a carcinogen in mice (Ref. 1).

Residual amounts of reactants, such as *p*-toluidine and other manufacturing aids, are commonly found among the constituents of many color additives. The presence of such impurities is not unique to color additives, however. Numerous contaminants are unavoidably present in all chemical products, even in highly purified reagent grade chemicals.

II. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 (Pub. L. 94-295), Congress mandated the listing of color additives for use in or on medical devices where the color additive comes in direct contact with the body for a significant period of time (21 U.S.C. 376(a)). The petitioned for use of D&C Green No. 6 is subject to this listing requirement. D&C Green No. 6 is added to these contact lenses in such a way that at least some of the color additive will come in contact with the eye and the fluids of the eye when the lenses are worn. In addition, the lenses are intended to be placed in the eye for several hours a day each day for 1 year or more. Thus, the color additive will come in direct contact with the body for a significant period of time.

III. The Use of D&C Green No. 6 in Contact Lenses

Only a small amount of a color additive is required to tint contact lenses. For the lenses in the petitions currently before the agency, the levels of D&C Green No. 6 used range from about 0.005 percent to 0.03 percent. For lenses weighing 40 milligrams each (the weight of the heaviest lens in the petitions), if a lens is tinted with 0.03 percent of D&C Green No. 6, there would be approximately 12 micrograms of D&C Green No. 6 in each lens or approximately 24 micrograms in a pair of lenses. If all the color additive migrated to the eye from the lens in 1 year, the average lifetime for a pair of contact lenses, the wearer would be exposed to 0.066 microgram of D&C Green No. 6 per day. In listing D&C Green No. 6 for external drug and cosmetic use, FDA estimated that the potential daily topical human exposure to this color was approximately 200 micrograms per day.

IV. Analysis of Data

A. *Safety of D&C Green No. 6.* Under section 706(b)(4) of the act (21 U.S.C. 376(b)(4)), the so-called "general safety clause" for color additives, a color additive cannot be listed for a particular use unless the data presented to FDA establish that the color is safe for that use. Although what is meant by "safe" is not explained in the general safety clause, the legislative history of the Color Additive Amendments of 1960 (Pub. L. 86-618) makes clear that this

word is to have the same meaning for color additives as for food additives.

"Safety" is defined in the legislative history of the Food Additives Amendment of 1958 as a "reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance." S. Rep. No. 2422, 85th Cong., 2d Sess. 6 (1958). This concept of safety is incorporated in FDA's color additive regulations (21 CFR 70.3(i)). In addition, the anticancer or Delaney Clause of the color additive provisions (section 706(b)(5)(B) of the act (21 U.S.C. 376(b)(5)(B))) provides that a noningested color additive shall be deemed unsafe if it is found after tests that are appropriate for evaluating the safety of the additive for such use to cause cancer in man or animals.

The petitioners have submitted the results of several studies to establish that there is a reasonable certainty of no harm from use of D&C Green No. 6 in contact lenses. These studies include cytotoxicity studies with the color additive, acute eye irritation studies in rabbits with extracts from the tinted lenses, and clinical studies in humans with the tinted contact lenses. In addition to these data, in assessing the safety of this use of the color additive, the agency has considered the safety data previously submitted to support listing of D&C Green No. 6 for use in external drugs and cosmetics and in sutures, including ophthalmic sutures. In the preamble to the final rule listing D&C Green No. 6 for external drug and cosmetic use, the agency stated that the sponsor had not submitted sufficient information to support the listing of the color additive for eye area use (47 FR 14138, 14139). Although the agency has now determined that the available data support the safety of the color additive for use in contact lenses, this fact does not alter FDA's finding that the data are not sufficient to establish the safety of use of D&C Green No. 6 in coloring drugs and cosmetics for eye area use. The latter use would subject the eye to substantially higher levels of the color additive than would use in contact lenses.

Although D&C Green No. 6 itself has not been shown to cause cancer, it does contain a carcinogenic impurity. For the reasons discussed in the preamble to the April 2, 1982 final rule listing D&C Green No. 6 for use in externally applied drugs and cosmetics, FDA has concluded that in determining whether the use of a color additive that has not been shown to cause cancer, but that does contain a carcinogenic impurity, is safe, the agency can rely in part on its calculations of the upper limit of risk from lifetime exposure to the carcinogenic impurity. (See 47 FR 14140–14145.) Evaluation of the risk from exposure to *p*-toluidine from uses of color additives in which *p*-toluidine is an impurity has two parts: (1) An assessment of probable exposure to *p*-toluidine from all uses of such color additives and (2) an extrapolation of the risk from *p*-toluidine observed in the animal bioassay (Ref. 1) to the conditions of probable exposure for humans (47 FR 14143).

B. *Prior FDA Actions on D&C Green No. 6 and Other Color Additives Containing p-Toluidine.* FDA has permanently listed six color additives in which *p*-toluidine is present or expected to be present in very small amounts as an impurity: D&C Violet No. 2 (21 CFR 74.1602, 74.2602, 82.1602); Ext. D&C Violet No. 2 (21 CFR 74.2602a); D&C Green No. 6 (21 CFR 74.1206); D&C Green No. 5 (21 CFR 74.1205); and D&C Red No. 6 (21 CFR 74.1306, 74.2306) and D&C Red No. 7 (21 CFR 74.1307, 73.2307). In the preambles to the final rules listing D&C Green No. 5 (47 FR 24278; June 4, 1982), D&C Green No. 6 (47 FR 14138; April 2, 1982), and D&C Red No. 6 and D&C Red No. 7 (47 FR 57681; December 28, 1982), FDA used two quantitative risk assessment procedures to extrapolate from the dietary dose in the animal experiment to the very low levels of human exposure. Neither of these procedures are likely to underestimate the actual risk from very low levels of exposure. Each procedure serves as a basis for the agency to determine to a reasonable certainty whether any harm will result from the possible exposure to *p*-toluidine from the use of these color additives.

In the D&C Green No. 6 rulemaking proceeding, FDA assessed the upper limit of lifetime risk from oral exposure to *p*-toluidine from use of D&C Green No. 6 to be less than 1 in 15 million to less than 1 in 150 million. Likewise, for D&C Green No. 5, FDA calculated that the upper limit lifetime risk from oral exposure to *p*-toluidine as a result of use of this color additive to be less than 1 in 30 million to less than 1 in 300 million. FDA has calculated that the upper limit lifetime risk from oral exposure to *p*-toluidine from use of D&C Red No. 6 and D&C Red No. 7 is less than 1 in 50 million to less than 1 in 500 million.

Detailed risk assessment analyses have not been performed for possible exposure to *p*-toluidine from the use of Ext. D&C Violet No. 2 or D&C Violet No. 2. However, FDA estimates the exposure to *p*-toluidine from the use of these color additives is in the same range as with D&C Green No. 6, because use limitations and specifications are similar, providing approximately the same level of risk.

As the agency stated in the final rule on D&C Red No. 6 and D&C Red No. 7, the upper limit of combined risk from the use of these six color additives is so low that the exposure to *p*-toluidine from the use of these color additives is safe.

C. *Assessment of Risk from Exposure to p-Toluidine from Proposed Use of D&C Green No. 7.* Based on the data submitted in the petitions for use of D&C Green No. 6 in contact lenses and other relevant information, FDA has made a risk analysis on the potential human exposure to *p*-toluidine. FDA based this calculation on the highest requested level of 0.03 percent by weight of D&C Green No. 6 in each of two contact lenses. Thus, as stated above, a 40 milligram contact lens, the heaviest lens included in the petitions, would contain 12 micrograms of D&C Green No. 6. Data on the amount of *p*-toluidine in D&C Green No. 6 indicate that the color additive would generally contain no more than 500 parts per million of *p*-toluidine. (See discussion of specifications for D&C Green No. 6 at 47 FR 14145.) Thus, the 24 micrograms of D&C Green No. 6 contained in two contact lenses tinted at 0.03 percent with D&C Green No. 6 would generally contain no more than 12 nanograms of *p*-toluidine. In its risk analysis, the agency assumed that a wearer would be exposed to and absorb 100 percent of the *p*-toluidine in a pair of lenses in 1 year. It was also assumed that chronic systemic exposure to D&C Green No. 6 via ocular route presents the same systemic risk as chronic dietary exposure. However, the agency chose the 1-year period because it is the average replacement rate for a pair of contact lenses.

On the basis of these premises, FDA has calculated that the upper limit of lifetime risk from exposure to *p*-toluidine from the use of D&C Green No. 6 in contact lenses is less than 1 in 10 billion. This amount of exposure to *p*-toluidine and the resulting level of risk is trivial and would not add in any appreciable way to the risk presented by other uses of D&C Green No. 6 or by use of other approved color additives that contain *p*-toluidine impurities.

V. Conclusion

Based upon the available toxicity data including the results of clinical trials, the low level of the color additive added to

the contact lens, the agency's exposure calculation, and the extremely low risk for *p*-toluidine, FDA finds that the color additive D&C Green No. 6 is safe for use in contact lenses at the levels requested in the petitions.

In accordance with § 71.15(a) (21 CFR 71.15(a)), the petitions and the documents that FDA considered and relied upon in reaching its decision to approve the petitions are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in § 71.15(b), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

This document adds a new Subpart D to 21 CFR Part 74 that provides for listing certified color additives for use in or on medical devices. In a future issue of the **Federal Register**, FDA will add to Subpart D medical devices currently listed in Subpart B—Drugs (e.g., sutures which are now medical devices, but which were regulated as drugs before the passage of the Medical Device Amendments).

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The agency's finding of no significant impact may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

Reference

The following information has been put on file at the Dockets Management Branch (address above) and is available for review in that office between 9 a.m. and 4 p.m., Monday through Friday.

1. Weisburger, E. K., et al., "Testing of Twenty-one Environmental Aromatic Amines or Derivatives for Long-Term Toxicity or Carcinogenicity," *Journal of Environmental Pathology and Toxicology*, 2:325:356, 1978.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371(e), 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 74 is amended by adding a new Subpart D, to read as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

Subpart D—Medical Devices

§ 74.3206 D&C Green No. 6.

(a) *Identity.* The color additive D&C Green No. 6 shall conform to the identity requirements of § 74.1206(a).

(b) *Specifications.* The color additive D&C Green No. 6 for use in contact lenses shall conform to the specifications of § 74.1206(b)(2).

(c) *Uses and restrictions.* (1) The color additive D&C Green No. 6 may be safely used to color contact lenses at levels not to exceed .03 percent by weight of the contact lens material.

(2) Authorization for this use shall not be construed as waiving any of the requirements of sections 510(k) and 515 of the Federal Food, Drug, and Cosmetic Act with respect to the contact lens in which D&C Green No. 6 is used.

(d) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of D&C Green No. 6 shall be certified in accordance with regulations in Part 80 of this chapter.

Any person who will be adversely affected by the foregoing regulation may at any time on or before April 28, 1983 submit to the Dockets Management Branch (address above) written objection thereto. Objections shall show how the person filing will be adversely affected by the regulation, specify with particularity the provisions of the regulation deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of 21 CFR 71.30. If a hearing is requested, the objections shall state the issue for the hearing, shall be supported by grounds factually and legally sufficient to justify the relief sought, and shall include a detailed description and analysis of the factual information intended to be presented in support of the objections in the event that a hearing is held. Three copies of all documents shall be filed and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective April 29, 1983, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be announced by publication in the **Federal Register**.

(Secs. 701(e), 706, 70 Stat. 919 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371(e), 376))

Dated: March 21, 1983.

Mark Novitch,

Deputy Commissioner of Food and Drugs.

[FR Doc. 83-7704 Filed 3-22-83; 10:47 am]

BILLING CODE 4160-01-M

---

21 CFR Parts 74, 81, and 82

[Docket No. 82N-0378]

Provisional Listing of D&C Red No. 6 and D&C Red No. 7; Postponement of Closing Date and Stay of Effectiveness

AGENCY: Food and Drug Administration.

ACTION: Final rule; stay of effective date.

SUMMARY: The Food and Drug Administration (FDA) is postponing the closing date for the provisional listing of D&C Red No. 6 and D&C Red No. 7 for general use as a color additive in drugs and cosmetics, except for use in the area of the eye. FDA is establishing a new closing date for D&C Red No. 6 and D&C Red No. 7 to give the agency time to complete evaluation of an objection received in response to the final regulation approving the petition for the permanent listing of D&C Red No. 6 and D&C Red No. 7. The regulation that permanently lists D&C Red No. 6 and D&C Red No. 7 and that removes them from the provisional list is stayed until the agency takes final action on the objection.

DATES: Effective March 29, 1983; the new closing date for D&C Red No. 6 and D&C Red No. 7 will be May 31, 1983.

FOR FURTHER INFORMATION CONTACT: John L. Herrman, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: FDA established the current closing date of March 29, 1983, for the provisional listing of D&C Red No. 6 and D&C Red No. 7 in a regulation published in the **Federal Register** of December 28, 1982 (47 FR 57681). The agency established the March 29, 1983 closing date for D&C Red No. 6 and D&C Red No. 7 to provide time for receipt and evaluation of any objections to the final regulation approving the petition for permanent listing of these color additives.

After the review and evaluation of the data relevant to the color additive petition to list D&C Red No. 6 and D&C Red No. 7 for use in drugs and cosmetics, the agency concluded that D&C Red No. 6 and D&C Red No. 7 were safe for general use in drugs and