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SMALL BUSINESS ADMINISTRATION

13 CFR Part 107

Small Business Investment Companies

AGENCY: Small Business Administration.

ACTION: Final rule.

SUMMARY: This final rule modifies the management-ownership diversity requirement in SBA's Small Business Investment Company (''SBIC'') Program to prohibit the ownership of more than 70% of a leveraged SBIC by any single investor or group of affiliated investors. An exception to the prohibition permits an investor that qualifies as a ''traditional investment company'', as determined by SBA, to own in excess of 70% of an SBIC. This final rule will help to ensure that each new leveraged SBIC has managers that exercise independence in managing the operations of the SBIC.

DATES: This rule is effective on December 29, 2000.

FOR FURTHER INFORMATION CONTACT: Leonard W. Fagan, at (202) 205–7583.

SUPPLEMENTARY INFORMATION: On August 14, 2000, SBA published a proposed rule (65 FR 49511) to revise the management-ownership diversity regulation in SBA's Small Business Investment Company (''SBIC'') Program. Under the proposal, no single investor or group of affiliated investors would be permitted to own or control more than 70% of a leveraged SBIC. SBA also proposed an exception to allow an entity qualifying as a ''traditional investment company'' to own and control more than 70% of an SBIC. SBA solicited comments on the proposed rule and specifically sought comment as to whether the proposed exception should be expanded to cover other categories of investors.

SBA received no comments on the proposed rule and, accordingly, is finalizing it without substantive change. SBA has made certain minor non-substantive edits to the proposed version of section 107.150 (''Management-ownership diversity requirement''), including relettering of the paragraphs, in order to conform to drafting requirements of the **Federal Register**.

The proposed rule summarized the changes in the management-ownership diversity regulation since its adoption in 1994. That summary and SBA's explanation of the proposed changes to the regulation, all of which have been implemented in this final rule, are repeated here as a convenience to the reader.

In 1994, SBA adopted a regulation requiring that all small business investment companies (''SBICs'') intending to issue participating securities have independence, or ''diversity'', between the management and the ownership of the company. 59 Fed. Reg. 16918 (April 8, 1994). This requirement of independence was designed to prevent the types of abuses that SBA had observed in SBICs owned and operated by a single individual or group of individuals. The abuses, which included conflict of interest transactions, misapplication of funds, and other types of self-dealing activities, had resulted in significant losses to SBA.

To satisfy the 1994 management-ownership diversity regulation, at least 30% of the capital of the SBIC had to be owned by investors who were neither Associates nor Affiliates of any Associates of the SBIC (as such terms were defined in 13 CFR Parts 107 and 121). In other words, at least 30% of the capital of the SBIC had to be owned by investors who were not part of the SBIC's management team and did not control the SBIC's management team. In general, three such ''diversity investors'' were required, but a single diversity investor would suffice if the investor was an entity that met certain net worth and regulatory oversight requirements.

The 1994 regulation permitted an SBIC with a parent company (*i.e.,* an investor owning greater than 50% of the SBIC) to treat the parent company's investors as if they were direct investors in the SBIC for purposes of demonstrating diversity. SBA would, in effect, ''look-through'' to the investors in the parent company for the desired independence from, and oversight of, the management of the SBIC.

In 1996, SBA extended the management-ownership diversity requirement to all new SBICs intending to use SBA financial assistance, or ''leverage'', whether the leverage was in the form of participating securities or debentures. 61 FR 3177 (January 31, 1996). SBA also replaced the automatic look-through provision described above with a discretionary look-through: SBA, in the exercise of its discretion, could look through to the parent's investors, but such treatment was no longer automatic. This change was in response to the increasing complexity SBA was encountering in ''drop-down'' SBICs (SBIC subsidiaries of larger companies), where the combination of multi-tiered organizational structures and other factors had led SBA to conclude that the necessary oversight by independent owners might not be present. SBA could still look through to the parent company's investors to find diversity, but would do so only if SBA believed that the result was consistent with the intent of the diversity regulation.

Later in 1996, Congress expressed its support for management-ownership diversity by enacting a statutory provision requiring SBA to ensure that the management of all new SBICs ''is sufficiently diversified from and unaffiliated with the ownership of the licensee in a manner that ensures independence and objectivity in the financial management and oversight of the investments and operations of the licensee.'' 15 U.S.C. 682(c); Public Law 104–208, section 208(c)(3) (September 30, 1996). SBA subsequently made minor changes to strengthen the management-ownership diversity regulation. These changes included requiring (1) that the diversity investors be unrelated to each other, (2) that each diversity investor have a significant ownership interest in dollar and percentage terms, and (3) that an SBIC's diversity be evidenced in its paid-in capital, not just its unfunded commitments. 63 FR 5859 (February 5, 1998).

As SBA stated in the proposed rule published on August 14, 2000, SBA believes that, overall, the management-ownership diversity regulation has been successful in encouraging the presence of investors who are truly independent of management. However, SBA has had

concerns as to whether independence was assured when a single investor, unrelated to the management team, owned substantially all of an SBIC.

To provide diversity under the regulation as in effect since 1994, the non-management interest was required to be at least 30% of the SBIC, but could have been as much as 100% and could have been owned by a single entity. This single super-majority investor could provide the required diversity from management as long as the investor did not control, was not controlled by, and was not under common control with, the managers of the SBIC. Thus, for diversity to be provided by a single super-majority investor who was otherwise unrelated to the SBIC's management team, SBA had to conclude that the investor did not control the SBIC's managers by virtue of the size of the investor's ownership interest in the SBIC.

As SBA explained in the proposed rule, SBA believes that the degree of influence that can be exerted by a super-majority investor may significantly reduce the management team's ability to act independently and objectively. The larger the size of an investor's ownership interest, the greater the investor's potential influence over the activities of the SBIC. This is true even if the investor is a passive limited partner.

At some ownership level, an investor's power to influence effectively becomes the power to control the managers of the SBIC, and the management team can no longer be said to have the ability to act independently. SBA's experience in administering the management-ownership diversity regulation persuaded it that it is difficult to objectively establish when that ownership level is reached. However, if the super-majority investor is limited to owning not more than 70%, and there is a 30% diversity investor that is independent of both the management and the super-majority investor, the super-majority investor's degree of potential influence on management becomes acceptable.

Accordingly, SBA proposed to amend the management-ownership diversity regulation, section 107.150, to prohibit ownership of more than 70% of a leveraged SBIC by a single investor or group of affiliated investors.

SBA recognized that there might be categories of investors who could be permitted to own in excess of 70% of an SBIC without destroying the SBIC's management-ownership diversity. SBA proposed an exception for one such category—the traditional investment company—a professionally managed firm organized exclusively to pool capital from more than one source for the purpose of investing in businesses that are expected to generate substantial returns to the firm's investors.

A subsidiary SBIC of such a traditional investment company can offer meaningful management-ownership diversity even if the investment company owns substantially all of the SBIC. This is true for a number of reasons. First, a traditional investment company has managers who are largely unrelated to and unaffiliated with the investors in the firm. These independent managers typically also serve as the managers of the subsidiary SBIC. Second, the managers of a traditional investment company and its subsidiary SBIC are properly authorized and motivated to make investments that, in their independent judgment, are likely to produce significant returns to all investors in the investment company and in the SBIC. Although the managers act independently of the investors in the firm, they are directly accountable to them. Most importantly, a traditional investment company benefits from the use of a subsidiary SBIC only if the SBIC makes profitable investments.

As SBA discussed in the proposed rule, SBICs with other types of super-majority investors do not necessarily present the same degree of management independence and objectivity, plus investor oversight. The objectives of other super-majority investors may include something other than profit maximization at the SBIC level. Large operating companies, for example, may profit from the use of a subsidiary SBIC other than through the financial performance of the SBIC. The SBIC might make strategic investments to support or otherwise benefit the non-investing activities of the operating company, rather than investments intended solely to contribute to the profitability of the SBIC. This would defeat one of the underlying purposes of management-ownership diversity—the protection of SBA's financial interest in the SBIC.

Under the final rule, a traditional investment company is permitted to own and control more than 70% of an SBIC.

In addition, the final rule adopts without change the proposed revisions to the 30% test (new paragraph (c) of section 107.150) in the management-ownership diversity regulation. Under those revisions, (1) publicly-traded licensees can no longer automatically satisfy the 30% test, (2) two new categories are added to the list of entities permitted to serve as the sole (30%) diversity investor in an SBIC, and (3) the scope of one of the other categories of entities on that list is clarified.

The first of those revisions is accomplished by deleting paragraph (a)(2) of the old diversity regulation. The second revision, the addition of two new categories of entities permitted to serve as the sole diversity investor, appears in new paragraphs (c)(1)(ii) and (iii) of section 107.150. The new categories are Institutional Investors that (1) are listed on the New York Stock Exchange or (2) are publicly-traded and meet the minimum numerical and corporate governance listing standards of that Exchange. Companies satisfying either of these listing standards have sufficient size and public oversight and visibility to justify treating them the same as regulated companies for purposes of the diversity regulation. SBA expects this change to resolve any uncertainty as to the requirements for a publicly-traded company to be considered acceptable to SBA as a single diversity investor under the regulation.

The third revision referred to above appears in new paragraph (c)(1)(i) of section 107.150. It makes clear that an entity seeking to qualify as the sole diversity investor because it is subject to government oversight or regulation must have its overall activities both regulated and periodically examined by a governmental authority satisfactory to SBA. U.S. federal and state bank regulators or insurance commissions are examples of satisfactory governmental authorities for this purpose. Regulation of an entity's health and safety activities by the Office of Safety and Health Administration (OSHA), on the other hand, would not be acceptable for this purpose.

An existing SBIC that is not currently required to have diversity will become subject to the new management-ownership diversity regulation only if (1) the SBIC applies for approval of a change of control and SBA requires diversity as a condition of its approval, or (2) the SBIC was not licensed with the expectation that it would issue leverage but it now seeks approval to do so.

As was proposed, SBA also is amending section 107.440(c) to clarify that SBA's approval of a change of control of an SBIC may be conditioned upon the licensee's compliance with the diversity regulation, as well as minimum capital requirements, then in effect. This has been SBA's practice since the diversity regulation was first adopted.

Compliance With Executive Orders 12866, 12988, and 13132, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Paperwork Reduction Act (44 U.S.C. Ch. 35).

This final rule is not a significant regulatory action for purposes of Executive Order 12866 and therefore was not reviewed by the Office of Management and Budget.

SBA has determined that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612. The purpose of the final rule is to redefine and clarify the concept of management-ownership diversity in an SBIC. The final rule will not apply to the approximately 365 companies currently licensed as SBICs, except in the insignificant number of cases where a transfer of control of the licensee occurs or where an SBIC that was not licensed with the expectation that it would issue leverage applies for such approval.

For purposes of Executive Order 12988, SBA has determined that this final rule is drafted, to the extent practicable, in accordance with the standards set forth in Section 3 of that Order.

For purposes of Executive Order 13132, SBA has determined that this final rule will have no federalism implications.

For purposes of the Paperwork Reduction Act, 44 U.S.C. Ch. 35, SBA has determined that this final rule contains no new reporting or recordkeeping requirements.

List of Subjects in 13 CFR Part 107

Investment companies, Loan programs—business, Reporting and recordkeeping requirements, Small businesses.

For the reasons stated above, the SBA amends 13 CFR part 107 as follows:

PART 107—SMALL BUSINESS INVESTMENT COMPANIES

1. The authority citation for part 107 continues to read as follows:

Authority: 15 U.S.C. 681 *et seq.*, 683, 687(c), 6887b, 687d, 687g and 687m.

2. Revise § 107.150 to read as follows:

§ 107.150 Management-ownership diversity requirement.

(a) *Diversity requirement.* You must satisfy the requirements in paragraphs (b), (c) and (d) of this section:

(1) In order to obtain an SBIC license (unless you do not plan to obtain Leverage),

(2) If at the time you were licensed you did not plan to obtain Leverage, but you now wish to be eligible for Leverage, or

(3) If SBA so requires as a condition of approval of your transfer of Control under § 107.440.

(b) *Percentage ownership requirement.* (1) Except as provided in paragraph (b)(2) of this section, no Person or group of Persons who are Affiliates of one another may own or control, directly or indirectly, more than 70 percent of your Regulatory Capital or your Leverageable Capital.

(2) *Exception.* An investor that is a traditional investment company, as determined by SBA, may own and control more than 70 percent of your Regulatory Capital and your Leverageable Capital. For purposes of this section, a traditional investment company must be a professionally managed firm organized exclusively to pool capital from more than one source for the purpose of investing in businesses that are expected to generate substantial returns to the firm's investors. In determining whether a firm is a traditional investment company for purposes of this section, SBA will also consider:

(i) Whether the managers of the firm are unrelated to and unaffiliated with the investors in the firm;

(ii) Whether the managers of the firm are authorized and motivated to make investments that, in their independent judgment, are likely to produce significant returns to all investors in the firm;

(iii) Whether the firm benefits from the use of the SBIC only through the financial performance of the SBIC; and

(iv) Other related factors.

(c) *Non-affiliation requirement.* (1) *General rule.* At least 30 percent of your Regulatory Capital and Leverageable Capital must be owned and controlled by three Persons unaffiliated with your management and unaffiliated with each other, and whose investments are significant in dollar and percentage terms as determined by SBA. Such Persons must not be your Associates (except for their status as your shareholders, limited partners, or members) and must not Control, be Controlled by, or be under Common Control with any of your Associates. A single ''acceptable'' Institutional Investor may be substituted for two or three of the three Persons who are otherwise required under this paragraph. The following Institutional Investors are ''acceptable'' for this purpose:

(i) Entities whose overall activities are regulated and periodically examined by state, Federal or other governmental authorities satisfactory to SBA;

(ii) Entities listed on the New York Stock Exchange;

(iii) Entities that are publicly-traded and that meet both the minimum numerical listing standards and the corporate governance listing standards of the New York Stock Exchange;

(iv) Public or private employee pension funds;

(v) Trusts, foundations, or endowments, but only if exempt from Federal income taxation; and

(vi) Other Institutional Investors satisfactory to SBA.

(2) *Look-through for traditional investment company investors.* SBA, in its sole discretion, may consider the requirement in paragraph (c)(1) of this section to be satisfied if at least 30 percent of your Regulatory Capital and Leverageable Capital is owned and controlled indirectly, through a traditional investment company, by Persons unaffiliated with your management.

(d) *Voting requirement.* (1) Except as provided in paragraph (d)(2) of this section, the investors required for you to satisfy diversity may not delegate their voting rights to any Person who is your Associate, or who Controls, is Controlled by, or is under Common Control with any of your Associates, without prior SBA approval.

(2) *Exception.* Paragraph (d)(1) of this section does not apply to investors in publicly-traded Licensees, to proxies given to vote in accordance with specific instructions for single specified meetings, or to any delegation of voting rights to a Person who is neither a diversity investor in the Licensee nor affiliated with management of the Licensee.

(e) *Requirement to maintain diversity.* If you were required to have management-ownership diversity at any time, you must maintain such diversity while you have outstanding Leverage or Earmarked Assets. To maintain management-ownership diversity, you may continue to satisfy the diversity requirement as in effect at the time it was first applicable to you or you may satisfy the management-ownership diversity requirement as currently in effect. If, at any time, you no longer have the required management-ownership diversity, you must:

(1) Notify SBA within 10 days; and

(2) Re-establish diversity within six months. For the consequences of failure to re-establish diversity, see §§ 107.1810(g) and 107.1820(f).

3. In § 107.440, revise paragraph (c) to read as follows:

§ 107.440 Standards governing prior SBA approval for a proposed transfer of Control.

* * * * *

(c) Require compliance with any other conditions set by SBA, including compliance with the requirements for minimum capital and management-ownership diversity as in effect at such time for new license applicants.

Dated: November 16, 2000.

Aida Alvarez,

Administrator.

[FR Doc. 00–30415 Filed 11–28–00; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Docket No. 99F–1912]

Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ultraviolet (UV) irradiation to reduce human pathogens and other microorganisms in juice products. This action is in response to a food additive petition filed by California Day-Fresh Foods, Inc.

DATES: This rule is effective November 29, 2000. Submit written objections and requests for a hearing by December 29, 2000.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William J. Trotter, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3088.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of June 25, 1999 (64 FR 34258), FDA announced that a food additive petition (FAP 9M4676) had been filed by California Day-Fresh Foods, Inc., 533 West Foothill Blvd., Glendora, CA 91741. The petitioner proposed that the food additive regulations in part 179 *Irradiation in the Production, Processing and Handling of Food* (21 CFR part 179) be amended to provide for the safe use of UV light to reduce human pathogens and other microorganisms in juice products.

II. Safety Evaluation

Under section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s)), a source of radiation used to treat food is defined as a food additive. The additive is not, literally, added to food. Instead, a source of radiation is used to process or treat food such that, analogous to other food processes, its use can affect the characteristics of the food. In the subject petition, the intended technical effect is a change in the microbial load of the food, specifically, a reduction of human pathogens and other microorganisms in juice products.

A. Toxicology

FDA has evaluated the safety of the use of UV irradiation to reduce human pathogens and other microorganisms in juices. This safety assessment was based on the current understanding of the effects of UV irradiation on the major chemical components of food. Having evaluated the data in the petition and other relevant material in the agency's files, the agency finds that any photochemical changes that may occur as a result of the UV irradiation are of no toxicological significance (Ref. 1).

B. Microbiology

The petitioner submitted data demonstrating the reduction of specific pathogens (*Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella*) inoculated into four types of juices (orange, apple, carrot, and garden vegetable). These four juice varieties are representative of the types of juice that are consumed by the U.S. population and that could be treated with UV irradiation (Ref. 2). After UV irradiation, there were significant reductions in pathogens. FDA concludes that the proposed use is effective in reducing human pathogens in juices and that treated juices will be at least as safe as untreated juices currently on the market (Ref. 3). However, the submitted microbiological data do not constitute the type of validation studies necessary to demonstrate the achievement of specific performance standards, *e.g.* 5-log reductions, for human pathogen control programs (Ref. 3). Therefore, users of this UV treatment who are subject to certain performance standards will need to establish that this treatment meets their required level of human pathogen reduction.

C. Specifications for Use

The petitioned UV radiation is produced by low pressure mercury lamps, which emit more than 90 percent of their light at 253.7 nanometers (nm) (2,537 Angstroms); juice being treated passes through a transparent tube in which the juice is subjected to UV irradiation. Because most juices strongly absorb UV radiation, most of the UV radiation would be absorbed by the juice at the wall of the tube near the source of the UV irradiation. However, the amount of UV irradiation that would reach juice in the middle of the tube would be insufficient to reduce significantly human pathogens. Therefore, the petitioner proposed that the juices flow under turbulent conditions that produce eddies and swirls in the juice to ensure that as much juice as possible will reach the wall of the UV transparent tube where the juice would be exposed to UV irradiation. This would help to reduce human pathogens and other microorganisms throughout the juice. The conditions for turbulent flow are described mathematically by the unitless Reynolds number (Re):

ER29NO00.001

where:
D is the tube diameter,
u is fluid velocity,
p is fluid density, and
μ is fluid viscosity.

To ensure that sufficient turbulent flow is achieved, the petitioner has requested that a limit of a Reynolds number of no less than 2,200 be incorporated into the regulation. FDA concurs with this specification (Ref. 4).

The amount of UV irradiation necessary for human pathogen reduction will depend on various factors, such as the type of juice, the initial microbial load, and the design of the irradiation system (*e.g.,* flow rate, number of lamps, and time exposed to irradiation). Therefore, FDA is not specifying a minimum or maximum dose by regulation, but concludes that this should be achieved for individual usage situations in a manner consistent with good manufacturing practice (Ref. 5). FDA expects that the maximum dose applied to the juice will be economically self-limiting due to the costs associated with UV irradiation. Additionally, the levels of UV irradiation applied to the juice will be limited by the possible alterations in organoleptic characteristics of the juice (*i.e.,* changes in taste or color) after UV irradiation, changes that may result in decreased consumer acceptance. Thus,