

the accompanying Opinion, has granted the appeal in part, and denied the appeal in part. Therefore,

It is ordered that the initial decision of the administrative law judge, pages 1-53, and appendices, be adopted as the Findings of Fact and Conclusions of Law of the Commission, except as is otherwise inconsistent with the attached opinion.

Other Findings of Fact and Conclusions of Law of the Commission are contained in the accompanying Opinion.

It is further ordered that the following Order to Cease and Desist be entered:

Order

I

It is ordered that respondents Litton Industries, Inc., a corporation, Litton Systems, Inc., a corporation, and their successors, assigns, officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising for sale, sale, or distribution of microwave ovens (either for commercial or consumer use), in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, do cease and desist from:

1. Representing, directly or by implication, that any commercial microwave oven or consumer microwave oven

(a) is able to perform in any respect, or has any characteristic, feature, attribute, or benefit; or

(b) is superior in any respect to any or all competing products; or

(c) is recommended, used, chosen or otherwise preferred in any respect more often than any or all competing products,

unless and only to the extent that respondents possess and rely upon a reasonable basis for such representation at the time of its initial and each subsequent dissemination. Such reasonable basis shall consist of competent and reliable surveys or tests and/or other competent and reliable evidence which substantiates the representation. A competent and reliable survey or test means one in which persons qualified to do so conduct the survey or test and evaluate its results in an objective manner, using procedures that insure accurate and reliable results.

2. Failing to maintain accurate records

(a) Of all materials that were relied upon in disseminating any representation covered by paragraph I(1) of this order, insofar as the text of such representation is prepared,

authorized, or approved by any person who is an officer or employee of respondents, or of any division, subdivision or subsidiary of respondents, or by any advertising agency engaged for such purposes by respondents, or by any of its divisions or subsidiaries;

(b) of all test reports, studies, surveys, or demonstrations that contradict any representation made by respondents that is covered by paragraph I(1) of this order.

Such records shall be retained by respondents for three years from the date that the representations to which they pertain are last disseminated, and may be inspected by the staff of the Commission upon reasonable notice.

It is further ordered that respondents Litton Industries, Inc., a corporation, Litton Systems, Inc., a corporation, and their successors, assigns, officers, agents, representatives, and employees, directly or through any corporation, subsidiary, division, or other device, in connection with the advertising for sale, sale, or distribution of microwave ovens (either for commercial or consumer use) and any other product normally sold to members of the general public for their personal or household use in or affecting commerce as "commerce" is defined in the Federal Trade Commission Act, do cease and desist from:

1. Misrepresenting in any manner, directly or by implication, the purpose, sample, content, reliability, results, or conclusions of any survey or test.

2. Advertising the results of a survey unless the respondents in such survey are a census or a representative sample of the population referred to in the advertisement, directly or by implication. A representative sample need not be a probability sample so long as when the ad is first disseminated respondents have a reasonable basis to expect the sampling method used would not produce biased results.

3. Representing, directly or by implication, that experts were surveyed, unless reasonable care was taken to insure that the survey respondents possessed sufficient expertise to qualify as respondents for the survey and to answer the survey questions. For purposes of this order, an "expert" is an individual, group or institution held out as possessing, as a result of experience, study or training, knowledge of a particular subject, which knowledge is superior to that generally acquired by ordinary individuals.

It is further ordered that the respondents shall, within sixty (60) days after service upon them of this order, file with the Commission a report in writing, setting forth in detail the manner and

form in which they have complied with this order.

It is further ordered that the respondents shall forthwith distribute a copy of this order to each of their operating divisions.

It is further ordered that the respondents shall notify the Commission at least thirty (30) days prior to any proposed change in the corporate respondents such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of this order.

By the Commission. Commissioner Bailey did not participate.

Carol M. Thomas,
Secretary.

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SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 231

[Release No. 33-6281]

Employee Benefit Plans

AGENCY: Securities and Exchange Commission.

ACTION: Interpretive release

SUMMARY: The Commission has authorized the issuance of an interpretive release supplementing an earlier release which expressed the views of its staff on the application of the Securities Act of 1933 to employee benefit plans. The purpose of the supplemental release is to provide further guidance and assistance to employers and plan participants in complying with that Act. To accomplish this purpose, the release: (1) clarifies certain positions expressed in the prior release, (2) discusses issues not previously addressed, and (3) describes recent developments under the 1933 Act relevant to employee benefit plans.

FOR FURTHER INFORMATION CONTACT: Peter J. Romeo, Chief Counsel, Division of Corporation Finance, Securities and Exchange Commission, Washington, D.C. 20549, (202) 272-2573.

SUPPLEMENTARY INFORMATION: On February 1, 1980, the Commission issued Release No. 33-6188 ("Release 6188") [45 CFR 8960], setting forth the views of its Division of Corporation Finance (the "staff") concerning the application of the Securities Act of 1933 ("1933 Act") [15 U.S.C. 77a et seq.] to employee benefit

plans.¹ The release was intended to resolve much of the uncertainty concerning the application of the 1933 Act which had developed as a result of the Supreme Court's decision in *International Brotherhood of Teamsters v. Daniel* ("Daniel").²

In Release 6188, the staff invited interested members of the public to express their views on the positions set forth in the release. Further, it indicated a willingness to reconsider those positions if it received persuasive comments from the public that revisions were appropriate.

The staff received 12 letters commenting on the release. Almost all of the letters expressed general agreement with the views of the staff. Several, however, either indicated reservations about the staff's position on certain issues or sought clarification of some matters not specifically addressed in the release. In addition to the written commentary, many persons have sought the views of the staff on numerous other issues relating to employee benefit plans not discussed in the release.

The various comments received indicate that there is considerable interest on the part of the public in receiving further guidance concerning the application of the 1933 Act to employee benefit plans. As a result, the Commission has authorized the issuance of this release for the purpose of providing additional advice by the staff on this subject. Among other things, the release will discuss issues not covered in the prior release, describe important developments in the employee benefit plan area that have occurred since that release was issued, and address concerns expressed by the persons who commented on the earlier release.

The release is divided into four topical areas, which are as follows:

- I. Plans Subject to the Act
- II. The Section 3(a)(2) Exemption
- III. Sales and Resales of Employer Stock
- IV. Form S-8

The statements set forth in this release represent the current views of the staff. Accordingly, they supersede

any prior letters or other documents issued by the staff on the subjects covered. Again, as with the earlier release, the staff welcomes any comments from the public on the positions expressed herein.³

I. Plans Subject to the Act

In Release 6188 the staff expressed the view that the only types of employee benefit plans which are subject to the 1933 Act are those which are both voluntary and contributory on the part of participating employees. Some questions were raised in this regard about the types of plans that are considered "voluntary and contributory." Further, some commentators asked for clarification or reconsideration of the staff's views concerning specific types of voluntary contributory plans. These matters are discussed under appropriate captions in the sections which follow.

A. Voluntary Contributory plans

The staff indicated in Release 6188 that a "voluntary" plan is "one in which employees may elect whether or not to participate."⁴ A "contributory" plan was defined as "one in which employees make direct payments, usually in the form of cash or payroll deductions, to the plan."⁵

In retrospect, the foregoing definitions were somewhat incomplete in that they did not encompass all types of voluntary contributory plans. Generally, it is the staff's view that the determination of whether a plan is a voluntary contributory one rests solely on whether the participating employees can decide at some point whether or not to contribute their own funds to the plan.⁶ Thus, for example, each of the following types of plans would be considered voluntary and contributory because each permits employees to make a determination, either at the time they join the plan or later, whether they will invest their own money: (1) a plan which is voluntary as to participation and then mandatory as to the amount of contributions, (2) a plan which is voluntary as to participation and which permits employees to make contributions at their option, and (3) a plan which is mandatory as to

participation but provides employees with a choice whether or not to invest their own funds.

Although the staff continues to hold the view that all voluntary contributory plans are subject to the 1933 Act, it should be noted that there exists litigation⁷ which raises the issue whether this view is appropriate with respect to a defined benefit plan⁸ which is voluntary and contributory. The Commission has filed an *amicus curiae* brief in the subject litigation taking the position that employee interests in the plan at issue are securities within the meaning of the 1933 Act.

B. Section 401(k) Plans

In connection with the foregoing, several persons have inquired whether cash or deferred arrangements qualifying under Section 401(k) of the Internal Revenue Code of 1954 as amended ("Code") [26 U.S.C. 401(k)] are deemed to be voluntary contributory plans. Section 401(k) exempts from taxation certain nondiscriminatory profit-sharing or stock bonus plans which allow employees to elect annually either (1) to receive immediate payment of the employer's plan contribution or a portion thereof, or (2) to defer receipt of, and not be subject to income tax on, the contribution or a portion thereof and have it invested in a trust where it will accumulate for later payment. The fact that employees can elect either to receive their shares of the employer's contribution immediately or to defer receipt raises a question whether the deferred amounts are tantamount to voluntary contributions by the employees.

The staff's view on the above question is that Section 401(k) plans are not contributory on the part of employees⁹ because they do not involve out-of-pocket investments by employees of their own funds. Such plans are funded entirely by employer contributions. Accordingly, in the staff's view, interests in Section 401(k) plans are not subject to the 1933 Act.

¹ As used in this release, the term "employee benefit plan" means a pension, profit-sharing, bonus, thrift, savings or similar plan. Thus, it generally would include plans described in Section 3(2) of the Employee Retirement Income Security Act of 1974 ("ERISA") [29 U.S.C. 1001 et seq.]. The term does not include welfare and similar plans, such as those described in Section 3(1) of ERISA, which do not involve any expectation of financial return or profit on the part of participating employees.

² 439 U.S. 551, 99 S. Ct. 790 (1979). In *Daniel*, the Supreme Court held that neither the 1933 Act nor the Securities Exchange Act of 1934 ("1934 Act") [15 U.S.C. 78a et seq.] applies to a compulsory noncontributory pension plan.

³ Any such comments should be addressed to Peter J. Romeo, Chief Counsel, Division of Corporation Finance, Securities and Exchange Commission, Washington, D.C. 20549.

⁴ See fn. 19 of Release 6188.

⁵ See fn. 20 of Release 6188.

⁶ As noted in Release 6188 (see the text at fn. 84), a plan may also be deemed to be voluntary and contributory and therefore to involve a sale of a security in those instances where participating employees individually bargain to contribute their services in exchange for interests in the plan.

⁷ *Newkirk v. General Electric Company*, [1979-1980 Transfer Binder] CCH Fed. Sec. L. Rep. 197,216 (N.D. Cal., 1979), appeal pending (9th Cir.), docket No. 80-402.

⁸ A defined benefit plan pays fixed or determinable benefits and in this respect differs from defined contribution plans, which pay benefits that vary, depending on the amount of plan contributions, the investment success of the plan, and allocations made of benefits forfeited by non-vested participants who terminate employment. See in this regard Section 3(34) of ERISA.

⁹ The Internal Revenue Service has taken a similar position under the Code. See Rev. Rul. 80-16, C.B.— (January 7, 1980), Internal Revenue Bulletin No. 1980-3, January 21, 1980.

C. Participant-Directed Plans

One of the commentators on Release 6188 questioned whether voluntary contributory plans which permit participants to direct the investment of their funds involve separate employee interests that are subject to the 1933 Act. Examples of such plans are Individual Retirement Account ("IRA") plans and certain Keogh and corporate plans which provide a variety of investment alternatives to participants.

The commentator's doubt is based in part on the belief that there is no investment contract relationship between the participant and the plan because the participant arguably does not rely on the plan to determine how his funds will be invested. Moreover, the commentator believes that there is no sale of an interest by the plan to the participant, on the theory that the participant makes no investment decision regarding such an interest.

Whether a separate security in the form of a plan interest exists in participant-directed plans depends on the circumstances.¹⁰ Certainly, as noted in Release 6188,¹¹ there is considerable doubt in this regard with respect to many master trust or prototype plan arrangements which are used to market IRAs and Keogh plans. Where the sponsor under such a trust or arrangement acts as a mere custodian of the participant's account without rendering investment advice or commingling the assets of the account with those of other accounts, and the participant retains complete investment discretion and control over the account, the staff generally has taken a no-action position regarding the registration of interests in the plan or arrangement.

A different situation exists where the sponsor or trustee of a participant-directed plan actively manages the funds provided to him by plan participants. Thus, for example, corporate thrift, savings or similar plans which allow participants to direct their investments into any of several investment funds managed by the plan trustees or administrators would be deemed to involve securities in the form of employee interests. In such cases, it is clear that the employees are relying on the plan managers to maintain the various funds in a manner that will produce profits and thereby enhance their investment. Although the interests of employees in such plans are

securities, they usually are exempt from registration under Section 3(a)(2) of the 1933 Act, except in those instances, as noted later in this release,¹² where employee monies are used to purchase employer stock.

D. TRASOPs

TRASOPs are a special form of Employee Stock Ownership Plan created by the Tax Reduction Act of 1975.¹³ From the employee's standpoint, they are a combined stock bonus and stock purchase plan. That is, employees are awarded shares of the employer's stock at no cost to them under such a plan, and they also may be given the opportunity to purchase additional shares at half the prevailing market price.

In Release 6188, the staff revised its prior position concerning TRASOPs and indicated that shares acquired in the open market by employees pursuant to such a plan henceforth need not be registered under the 1933 Act, provided the plan satisfied certain conditions described in Release No. 33-4790 ("Release 4790") (July 13, 1965) [30 FR 9959].¹⁴ One of the conditions in Release 4790 is that the plan must not contain any significant limitations on the right of employees to withdraw which might give rise to separate employee interests.

Several persons, noting that all TRASOPs contain a mandated provision which generally prohibits withdrawals for a period of seven years, inquired whether the above condition means that interests in an open market TRASOP must be registered. The staff's view is that the mandated seven-year withdrawal provision will not, by itself, necessitate the registration of employee interests in a TRASOP. To hold otherwise would subject all open market TRASOPs to registration, thereby nullifying the perceived benefits of the staff's position in Release 6188. In effect,

¹² See Part II, Subsection B. 1.

¹³ Pub. L. 94-12 (March 29, 1975). Employers derive certain tax benefits by sponsoring TRASOPs. They can, for instance, receive up to an additional one percent investment tax credit for amounts contributed in cash or shares to the plan. In addition, they can become entitled to an extra one-half percent investment tax credit to the extent they match employee contributions for the purchase of company stock under the plan.

¹⁴ The conditions in Release 4790 are designed to provide some assurance that the purchase of stock pursuant to the plan will be essentially the same as a purchase by the employee in an open-market transaction. Among the conditions are requirements that the employer limit its participation in the plan basically to performing ministerial functions and that it not pay any portion of the purchase price of stock acquired by employees under the plan. When such conditions are satisfied, the employer is not considered to be soliciting offers to buy its securities within the meaning of Section 2(3) of the 1933 Act.

the conditions in Release 4790 relating to withdrawal rights and employer contributions¹⁵ are not considered applicable to open market TRASOPs.

Accordingly, if a TRASOP is in compliance with the other conditions outlined in Release 4790, neither the stock acquired by employees nor any plan interests that might be deemed to exist would have to be registered under the 1933 Act.

Finally, a number of persons asked whether an issuer which decides to discontinue registration of its TRASOP under the 1933 Act because of the staff's revised position in Release 6188 must formally notify the Commission or its staff regarding that fact. The staff encourages an issuer in such a situation to furnish formal notification by filing a post-effective amendment to its registration statement formally deregistering the remaining unsold shares.¹⁶ The principal advantage of deregistration is that it makes clear on the record that the plan is relieved from any obligation to file future periodic reports that otherwise might be required under Section 15(d) of the 1934 Act. However, a failure to formally notify the Commission will not mean that a TRASOP continues to be subject to registration or that it cannot avail itself of the staff's position concerning the nonregistration of open market TRASOPs. In effect, therefore, formal deregistration is encouraged but is not absolutely necessary.¹⁷

E. Open Market Stock Purchase Plans

As a result of the staff's position in Release 6188 that certain open market TRASOPs no longer need be registered, a number of persons have asked the staff to take a similar position with respect to all other open market stock purchase plans which currently must be registered because the employer pays part of the purchase price of the stock acquired by employees. Traditionally, the payment by the employer of part of the purchase price has been considered a solicitation of an offer to buy its securities within the meaning of Section 2(3) of the 1933 Act and has therefore triggered the registration provisions of the Act.

¹⁵ See Release 6188 [Subsection B.2] and the next section of this release for discussions of employer contributions to TRASOPs.

¹⁶ Even in the absence of formal notification, the registration statement automatically could no longer be used after a period of time because it would fail to satisfy the current prospectus requirements of Section 10(a)(3) of the 1933 Act.

¹⁷ See in this regard the staff's no-action letter concerning *The Limited Stores, Inc.* dated August 8, 1980.

¹⁰ Although the plan interests may not always be deemed securities, the stocks, bonds or investment fund shares in which the participant directs that his assets be invested would be securities in almost all instances.

¹¹ See the text beginning at fn. 76 of Release 6188.

In Release 6188,¹⁸ the staff stated with respect to open market TRASOPs that "no practical purpose appears to be served by requiring registration solely because the employer is paying half the purchase price." In part, this position reflected the general policy of the Congress to encourage the adoption of TRASOPs by employers. This policy is evidenced by the fact that the federal government, through the device of an additional investment tax credit, in effect reimburses employers for their contributions to the cost of stock acquired by employees under such plans.

In the case of a non-TRASOP open market stock purchase plan which provides for contributions by the employer that match or exceed employee contributions, the employer's contributions are not reimbursed by the federal government. Notwithstanding this fact, it seems reasonable to not require registration where such a plan otherwise satisfies the requirements of Release 4790. From the employee's standpoint, the plan is similar to an open-market TRASOP. The source of half or more of the funds used to purchase stock is the employer, and the employee has a strong incentive (though is not actually required) to participate because his risk of loss is substantially reduced due to the matching contribution feature. Under the circumstances, particularly the limited investment required of participating employees, the staff henceforth will take a no-action position regarding the registration of all open market stock purchase plans which provide for employer contributions that match or exceed employee contributions and which otherwise satisfy the conditions of Release 4790.

The foregoing position is being taken for policy reasons. Accordingly, it should not be construed as a change in the view expressed in Release 4790 that contributions by employers under stock purchase plans to the purchase price of their stock generally constitute solicitations of offers to buy under Section 2(3). As a result, the staff's no-action position described above does not extend to other open market stock purchase plans under which employers make contributions which fail to match or exceed the contributions of participating employees.

On another matter relating to open market stock purchase plans, some persons inquired whether the staff continues to apply Release 33-5515 ("Release 5515") (August 8, 1974) [39 FR 28520] to such plans. The inquiry stems

from the fact that Release 6188 omitted any reference to Release 5515 when discussing open market plans.

Release 5515 states in part that an issuer may perform certain bookkeeping and similar administrative functions in operating a dividend reinvestment or similar plan without such activities being deemed solicitations of offers to buy its securities. The staff traditionally has applied the position stated in that release to open market employee stock purchase plans and continues to do so. Accordingly, the fact that Release 6188 did not specifically state that Release 5515 is applicable to such plans should not be construed as a change in the staff's prior position.

F. Conversions of Noncontributory Plans

In Release 6188¹⁹ the staff indicated that a conversion of an existing plan to another plan would involve a sale of a security if a choice were given to plan participants regarding the matter. A commentator asked the staff to reconsider that position with respect to conversions of noncontributory plans. First, he questioned whether a security is involved when an existing noncontributory plan is being converted to another plan, in view of the fact that interests in noncontributory plans are not deemed to be securities. Second, the commentator believes it is inconsistent for the staff to state, as it did in Release 6188, that registration is not required with respect to investment elections under noncontributory plans,²⁰ but may be necessary if employees are given a choice regarding the conversion of a noncontributory plan to another plan. In the commentator's opinion, the two situations should be treated the same because they both involve a choice by employees with respect to monies not contributed by them. Finally, he stated that the staff's position appears to have the undesirable effect of discouraging plan sponsors from providing employees with a choice regarding conversions, because to do so might subject the conversions to registration.

The staff has given serious consideration to the views described above. Nevertheless, it continues to believe that a conversion of a noncontributory plan involves a sale of a security where employees are given a choice as to whether they will receive funds or benefits from the original plan or whether they will have such funds invested on their behalf in another plan. In such a situation, although the funds from the original plan were derived from

the employer, the second plan operates essentially as a voluntary contributory one insofar as the contributions from the prior plan are concerned.

The staff believes that a conversion in which employees have the option to receive funds or to invest them in another plan can be distinguished from an election granted to employees under a continuing noncontributory plan. In a conversion where a choice is given, the employee's interest in the prior plan is terminated, and the funds or other benefits representing his accumulated rights under that plan in effect become the property of the employee, and can at his election be contributed to the new plan. As a result, it is appropriate to regard the funds contributed to the new plan as coming from the employee, and to consider the new plan as contributory to that extent. In the situation involving an election among investment media under an ongoing noncontributory plan, however, the funds contributed by the employer are not made available to the employee, but instead are retained by the plan itself and therefore cannot be regarded as employee monies. Similarly, under Section 401(k) plans, discussed in Section I.B. above, although the employee has an initial right to elect to receive plan contributions directly, amounts which are contributed come solely from the employer, become assets of a continuing plan, and can properly be regarded as not involving out-of-pocket investments by employees of their own funds.

In summary, it is the staff's view that conversions in which employees are offered a choice between a new plan and receipt of the funds or other benefits from the old plan involve a sale of a security subject to the 1933 Act. Many such conversions, however, would be exempt from registration under Section 3(a)(2) of the 1933 Act, provided none of the funds transferred are to be invested in employer stock and other applicable conditions are met.²¹

II. The Section 3(a)(2) Exemption

Section 3(a)(2) of the 1933 Act provides an exemption from registration for the issuance of securities in connection with employee benefit plans. The exemption was discussed at length in Release 6188. Subsequent to that release, Congress amended Section

²¹ There are, of course, situations where the Section 3(a)(2) exemption would not be available. For example, the exemption could not be relied upon if a defined benefit plan were converted to, and employees were given a choice as to investment in, a defined contribution profit sharing or stock bonus plan (including an employee stock ownership plan) under which the funds transferred on conversion were invested in employee stock.

¹⁸ See Part III, Subsection B. 1 of Release 6188.

¹⁹ See Part III, Section A. 1. of Release 6188.

²⁰ See Part III, Section A. 2. of Release 6188.

3(a)(2) in certain significant respects and the Commission proposed the adoption of a rule that would exempt certain Keogh plans under that section. These developments, as well as certain significant interpretive issues that were not addressed in Release 6188, are discussed in the sections which follow.

A. Important Developments

Title VII of the Small Business Investment Incentive Act of 1980 (the "1980 amendments")²² amended Section 3(a)(2) and certain other provisions of the federal securities laws relating to employee benefit plans.²³ The amendments to Section 3(a)(2) are set forth below. Italics and brackets have been used to signify, respectively, additions to and deletions from the former language of the section.

Section 3. (a) Except as hereinafter expressly provided, the provisions of this title shall not apply to any of the following classes of securities:

(2) * * * any interest or participation in a single [or collective] trust fund, or in a collective trust fund maintained by a bank, [or in a separate account maintained by an insurance company] or any security arising out of a contract issued by an insurance company, which interest, [or] participation, or security is issued in connection with (A) a stock bonus, pension, or profit-sharing plan which meets the requirements for qualification under section 401 of the Internal Revenue Code of 1954, (B) an annuity plan which meets the requirements for deduction of the employer's contributions under section 404(a)(2) of such Code, or (C) a governmental plan as defined in section 414(d) of such Code which has been established by an employer for the exclusive benefit of its employees or their beneficiaries for the purpose of distributing to such employees or their beneficiaries the corpus and income of the funds accumulated under such plan, if under such plan it is impossible prior to the satisfaction of all liabilities with respect to such employees and their beneficiaries, for a part of the corpus or income to be used for, or diverted to, purposes other than the exclusive benefit of such employees or their beneficiaries, other than any plan described in clause (A), [or] (B), or (C) of this paragraph (i) the contributions under which are held in a single trust fund [maintained by a bank] or in a separate account maintained by an insurance company for a single employer and under which an amount in excess of the employer's contribution is allocated to the purchase of securities [other than interests or participations in the trust or separate account itself] issued by the employer or any company directly or indirectly controlling, controlled by, or under common control with the employer, (ii) which covers employees

some or all of whom are employees within the meaning of section 401(c)(1) of such Code, or (iii) which is a plan funded by an annuity contract described in Section 403(b) of such Code. The Commission, by rules and regulations or order, shall exempt from the provisions of section 5 of this title any interest or participation issued in connection with a stock bonus, pension, profit-sharing, or annuity plan which covers employees some or all of whom are employees within the meaning of Section 401(c)(1) of the Internal Revenue Code of 1954, if and to the extent that the Commission determines this to be necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of this title.

The 1980 amendments broadened the scope of the Section 3(a)(2) exemption by including certain insurance contracts and governmental plans within its coverage. In addition, the amendments make clear that any security arising out of a contract issued by an insurance company will be exempt under Section 3(a)(2) if it is issued in connection with a plan specified in that section and the other conditions of the exemption are met. As revised, the exemption is now broad enough to include within its coverage guaranteed investment contracts²⁴ and other arrangements sold to tax qualified plans that are funded by an insurance company's general account rather than by separate accounts. Formerly, Section 3(a)(2) exempted only securities funded by separate accounts, with the result that new insurance contracts funded by general accounts arguably were beyond its coverage.²⁵

The 1980 amendments also added governmental plans, as defined in Section 414(d) of the Internal Revenue Code, to the category of plans to which securities of the type specified in Section 3(a)(2) may be offered and sold without registration under the 1933 Act. Section 414(d) was added to the Code in 1978 and provides special tax treatment for plans covering state and local governmental employees. In order to fall within the amended exemption, a Section 414(d) plan must be established for the exclusive purpose of providing retirement benefits to employees or their beneficiaries, and the funds of the plan

must be segregated and not subject to diversion to other purposes.

Finally, the 1980 amendments codified two prior staff interpretations regarding the Section 3(a)(2) exemption. First, the amendments specifically exclude from the exemption contracts issued in connection with tax deferred annuity plans described in Section 403(b) of the Internal Revenue Code. Such plans are adopted primarily by public school systems and departments of education, and it has been the staff's position that annuity contracts issued to them must be registered under the 1933 Act unless some exemption other than that provided by Section 3(a)(2) is available. Second, the amendments make it clear that a single trust fund need not be maintained by a bank in order for the Section 3(a)(2) exemption to be available. The former language of Section 3(a)(2) was ambiguous in this respect, but it is now clear that only collective trust funds for qualified plans must be maintained by a bank under the exemption.

The 1980 amendments are silent on the issue of whether Section 3(a)(2) exempts the interests of participants in plans covered by the exemption. The staff took the position in Release 6188 that, on the basis of the Commission's past administrative practice and practical considerations, Section 3(a)(2) generally exempts such interests to the same extent that it exempts the interests of plans in certain specified funding vehicles. The staff's position, which was contrary to dicta in the *Daniel* case,²⁶ recognized that the interests of participants in a plan are identical to their interests in the funding vehicles invested in by the plan and therefore generally should be accorded the same treatment as these latter interests.²⁷ Thus, for purposes of the Section 3(a)(2) exemption, the two types of interests generally are the same for all practical purposes. Nothing in the legislative history of the 1980 amendments suggests that the staff's interpretation is incorrect. Accordingly, the staff continues to adhere to the position outlined in Release 6188.

²² See the discussion in Release 6188 (part IV, Section B. 2.) on this point.

²³ There are limited situations, however, where the interests of participants in a plan would be treated differently under Section 3(a)(2) than the interests of the plan in certain funding vehicles. For example, a plan may invest part or all of its assets in a mutual fund. The interest of the plan in the mutual fund would not be exempt under Section 3(a)(2) because such funds are not referred to in the section. However, the interests of employees in the plan would be exempt under Section 3(a)(2) so long as no employee funds were invested in employer securities and the plan otherwise satisfied the requirements of the exemption.

²⁴ Pub. L. 96-477 (October 21, 1980).

²⁵ The other provisions amended were Section 3(a)(12) of the 1934 Act and Section 3(c)(11) of the Investment Company Act of 1940 ("1940 Act") [15 U.S.C. 81a et seq.].

²⁶ See Release No. 33-6051 (April 5, 1979) [44 FR 21626].

²⁷ Notwithstanding the former language of the Section 3(a)(2) exemption, the staff had taken a no-action position regarding the registration of guaranteed investment contracts issued to plans under certain specified conditions. Letter to American Council of Life Insurance dated March 18, 1977. The no-action position was based in part on a recognition that guaranteed investment contracts are relatively new forms of contracts that generally were not in existence in 1970 when Congress created the exemption for interests in separate accounts.

In addition to the enactment of the 1980 amendments, a further development of significance pertaining to Section 3(a)(2) was the issuance for public comment of proposed Rule 180 under the 1933 Act.²⁸ Pursuant to its authority in Section 3(a)(2) to exempt securities issued in connection with Keogh plans from registration, the Commission proposed the rule for the purpose of exempting plans which meet the criteria specified therein. The rule, if adopted, should largely eliminate the need for the Commission to issue exemptive orders for Keogh plans in the future.

B. Significant Interpretive Issues

There are several important issues relating to Section 3(a)(2) that various commentators have asked the staff to address. These are discussed below under appropriate captions.

1. Plans With Multiple Investment Choices.

Many persons have asked the staff to discuss the availability of the Section 3(a)(2) exemption for interests in thrift, savings or similar plans which provide employees with several investment alternatives, one of which consists of securities of the employer. It is the staff's view that the exemption is available for such interests only if amounts invested in securities of the employer can be attributed to contributions made by the employer. The staff bases its position on the provision in Section 3(a)(2) which states that the exemption does not apply to a plan whose contributions are held in a single trust fund or in a separate account maintained by an insurance company and under which an amount in excess of the employer's contribution is allocated to the purchase of securities of the employer or its affiliates. As previously noted in Release 6188,²⁹ this provision was included in Section 3(a)(2) in 1970 in order to reflect the staff's consistent administrative practice of not requiring interests in plans to be registered unless employee monies were used to buy securities of the employer.

The application of the staff's position to thrift and similar plans can best be illustrated by the following example. XYZ Company has established a thrift plan whose assets are held in a single trust fund. The plan's assets are segregated under the trust into three separate funds, one of which consists exclusively of XYZ securities. Employees may choose to have their plan contributions invested in any or all

of the funds, and XYZ will match all such contributions on a dollar-for-dollar basis. Aggregate contributions under the plan are as follows:

Three funds	Employee contributions (percent)	XYZ contributions (percent)	Total (percent)
XYZ securities fund	10	10	20
Guaranteed income fund	20	20	40
Diversified equity fund	20	20	40
Total	50	50	100

It is the staff's view that although XYZ's contributions to the plan in the aggregate exceed the amount invested in its securities, the Section 3(a)(2) exemption is not available. This is because the plan clearly allows, insofar as the XYZ securities fund is concerned, funds in excess of the employer's contribution to be allocated to the purchase of securities of the employer. Thus, interests in the plan are not exempt under Section 3(a)(2). If, however, the plan were changed so that it became possible to attribute all employee contributions to non-XYZ securities, the Section 3(a)(2) exemption would then be available. In the above example, this could be done in either of two ways. First, employees might be prohibited in the future from investing their own money in the XYZ securities fund, but they would be permitted to designate that matching contributions by the employer be invested on their behalf in that fund. Second, the XYZ securities fund might either be enlarged to include securities of other entities or merged into the diversified equity fund, with the understanding that in no instance would the amounts invested in XYZ securities under any such fund exceed the amount of XYZ's contributions to that fund. In both of these situations, it would be possible to attribute all investments in XYZ securities to contributions by the employer, with the result that the Section 3(a)(2) exemption would then be available, assuming all of its other conditions were satisfied.

2. Commingling of Assets in a Fund or Account.

In Release 6188,³⁰ the staff expressed the opinion that the Section 3(a)(2) exemption for interests or participations in a bank collective trust fund or an insurance company separate account is not available if the fund or account commingles the assets of tax qualified corporate plans with those of Keogh plans. The staff based its view on the belief that Section 3(a)(2) exempts only

interests or participations in collective funds or separate accounts which consist exclusively of assets of tax qualified corporate plans.

Representatives of insurance companies and other persons have asked the staff to reconsider the opinion noted above. Their request is based partly on the language and legislative history of Section 3(a)(2) and partly on practical considerations. With respect to the language of Section 3(a)(2), these persons noted that it exempts any interest or participation in a collective fund or separate account so long as it is issued in connection with a plan (other than a Keogh plan) qualified under Section 401 of the Internal Revenue Code. Read literally, this language does not preclude commingling of Keogh plan assets with corporate plan assets. Further, the legislative history of Section 3(a)(2) suggests that a literal interpretation is not inappropriate in this regard.³¹

From a practical standpoint, the persons requesting reconsideration point out that there does not appear to be any substantial reason why commingling of the assets of corporate and Keogh plans should be prohibited. Moreover, they indicate that a number of insurance companies commingled assets in separate accounts in such a manner for many years prior to the enactment of Section 3(a)(2) and have continued to do so after its enactment. Such companies traditionally have registered only the interests in such accounts that are sold to Keogh plans, believing that the Section 3(a)(2) exemption applied to the interests sold to tax qualified corporate plans.

After consideration of the reasons outlined above, the staff has determined to change the interpretation in Release 6188 discussed above. Accordingly, the availability of the Section 3(a)(2) exemption no longer will be deemed by the staff to depend in part on whether the assets of Keogh plans are commingled with the assets of tax qualified corporate plans. Of course, where commingling of assets in the above manner does occur, interests or participations sold to plans not covered by the Section 3(a)(2) exemption would be subject to registration under the 1933 Act, absent some other exemption.

3. Plans Funded by Exempt Securities.

The exemption from registration provided by Section 3(a)(2) for interests

²⁸ Release No. 33-6247 (October 14, 1980) [45 FR 69476].

²⁹ See the text at fn. 132 of Release 6188.

³⁰ See the text at fn. 114 of Release 6188.

³¹ Compare Amendment No. 438 to S. 1659, 90th Cong., 1st Sess., Section 102(b) (1967), which would have required a bank collective fund under Section 3(a)(2) to consist solely of assets of tax qualified plans other than Keogh plans, and a subsequent bill, S. 3724, 90th Cong., 2nd Sess., Section 27(b) (1968), which did not include the word "solely."

or participations in a plan is, by virtue of the language of the statute, not available in those instances where employee monies are used to purchase securities of the employer or its affiliates. Notwithstanding the language of Section 3(a)(2), the staff has taken a no-action position for policy reasons on several occasions where employee monies were used to purchase employer securities which were exempt from registration under one of the securities exemptions set out in Sections 3(a)(2) through 3(a)(8) of the 1933 Act.³² These no-action positions have been based on the view that it would be contrary to the purposes of Section 3(a)(2) to require interests in a plan to be registered solely because employees are investing in securities of the employer which, because of their nature, were never intended by Congress to be subject to registration.

On a somewhat related issue, a commentator on Release 6188 inquired whether the Section 3(a)(2) exemption would be jeopardized if the trustees for a plan whose assets are held in an insurance company separate account decided to create an additional fund consisting of exempt U.S. Government securities which is not maintained by the insurance company. The staff's position is that the exemption would not be affected by such a decision. Apart from the policy consideration previously noted that investments by a plan in exempt securities should not necessitate registration, it would appear that in this instance the plan's investment in U.S. Government securities would be held in a single trust fund that would satisfy the literal requirements of Section 3(a)(2). Accordingly, the exemption would be available, in the staff's view.

III. Sales and Resales of Employer Stock

Release 6188 discussed in considerable detail sales and resales of employer stock by plans and their participants. There still remain, however, several important matters that merit attention. These are discussed below.

³² See, e.g., letters re *Irwin Union Bank & Trust Co.* dated August 18, 1978 and *Roadway Express, Inc.* dated May 24, 1979. The Division's no-action positions in this area, however, do not extend to those situations in which the employer's securities are offered to employees in reliance upon a transactional exemption, such as those provided by Sections 3(a)(9) through 3(a)(11) of the 1933 Act. The reason is that, unlike a securities exemption, a transactional exemption does not rest on a Congressional determination that the securities themselves should be exempt from registration. See letter re *H.C. Prange Company* dated July 14, 1980.

A. Sales by Plans

In Release 6188,³³ the staff indicated that if a plan is considered an affiliate³⁴ of the employer, any sales by it of employer stock "would be subject to the registration and antifraud provisions of the 1933 Act in the same manner as if the employer were engaging in the transaction." Some persons have asked whether this statement was meant to imply that plans which are affiliates cannot use Rule 144 [17 CFR 230.144]³⁵ under the Act to sell employer stock. The basis for this inquiry lies in the fact that issuers are barred from using Rule 144 to sell their own stock, and thus it could be inferred from the staff's statement that plans which are affiliates of such issuers likewise are so barred.

The statement quoted above was not intended to preclude plans from using Rule 144 to sell employer stock. Only issuers are prohibited from using the rule. Thus, an affiliate plan may rely on Rule 144 to sell stock of the employer, provided it complies with all applicable conditions of that rule.

B. Resales by Plan Participants

The staff stated in Release 6188 that non-affiliates who receive unregistered securities from a plan could resell such securities immediately without any restrictions (such as registration or compliance with Rule 144) if three conditions were satisfied.³⁶ The three conditions are: (1) the issuer of the securities is subject to the periodic reporting requirements of Section 13 or 15(d) of the 1934 Act, (2) the stock being distributed is actively traded in the open market, and (3) the number of shares being distributed is relatively small in relation to the number of shares of that class issued and outstanding. Several persons have asked that the staff

provide some guidance as to what is considered to be a "relatively small amount" under the third condition noted above. In this regard, it is the staff's view that a relatively small amount will always be involved when the total amount of shares distributed by a plan to its participants during a fiscal year does not exceed one percent of the outstanding securities of the class. Distributions during a fiscal year which exceed the one-percent test may in some cases still be deemed to involve relatively small amounts if there is data (such as a large trading volume) indicating that resales of the distributed shares will not have a measurable impact on the trading market.

With respect to resales by affiliates, the staff indicated in Release 6188 that, even when the three conditions described above are satisfied, resales by such persons would continue to be subject to registration in the absence of an available exemption, such as that provided by Rule 144. In this regard, the staff also has stated that if the three conditions are complied with the securities involved will not be considered "restricted securities" under Rule 144.³⁷ As a result, affiliates may disregard the two-year holding period requirement of Rule 144 in the event they choose to rely on that rule for the resale of their securities.

IV. Form S-8

Form S-8 [17 CFR 239.16b] is the principal form used to register securities issued in connection with employee benefit plans.³⁸ In the last several months, the Commission and its staff have taken several steps designed to minimize the burdens imposed on issuers who use this form.

³³ Release 33-5750 (October 8, 1976) [41 FR 45632].

³⁴ Form S-8 can be used for offerings which are limited to employees of the issuer and its parents and subsidiaries, provided the following conditions are met: (1) the issuer, at the time of filing, has been subject to the periodic reporting requirements of Section 13 or 15(d) of the 1934 Act for at least the prior 90 days and has filed all reports required during the preceding 12 months or such shorter period that it was subject to those requirements, and (2) the issuer has furnished or will furnish an annual report to security holders for its last fiscal year containing substantially the information required by Rule 14a-3 [17 CFR 240.14a-3] under the 1934 Act. Those issuers who are unable to satisfy the requirements for the use of Form S-8 can use Form S-1 [17 CFR 239.11] or, if they qualify, Form S-7 [17 CFR 239.28], Form S-16 [17 CFR 239.27], or Form S-18 [17 CFR 239.38]. Issuers who utilize these other forms for registering primary offerings by employee benefit plans must include therein all of the information regarding the plans which Form S-8 would otherwise require. Thus, the disclosures regarding the plan would be the same, no matter which registration form was used.

³⁵ See Part V, Section B of Release 6188.

³⁶ An "affiliate" of an entity is defined in Rule 405 [17 CFR 230.405] under the 1933 Act as "a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the [entity]."

³⁷ Rule 144 provides a safe harbor from the registration provisions of the 1933 Act for the resale of restricted securities (i.e., securities acquired in non-public transactions from the issuer or an affiliate) and securities held by affiliates. It contains various conditions, including requirements that there be current information about the issuer available to the public and that the securities have been held by the seller for at least two years.

³⁸ An assumption underlying the staff's position is that the unregistered securities were distributed in a legal offering to plan participants. If the securities were issued in an illegal offering, non-affiliate participants not involved in the illegality could, pursuant to the policy underlying Section 4(3)(A) of the 1933 Act, freely resell such securities without regard to whether the three conditions were satisfied. For a discussion of Section 4(3)(A) of the Act, see 1 Loss, Securities Regulation (1961), p. 257, fn. 228.

A. Revisions to the form and to the Procedures for Making it Effective

The initial step taken by the Commission was to revise the procedures utilized by it for making filings on Form S-8 effective under the 1933 Act.³⁹ Formerly, registration statements on Form S-8 and post-effective amendments thereto generally were not made effective until the Commission's staff had reviewed the filings in question and was satisfied that they were in compliance with all applicable disclosure requirements. It became increasingly apparent to the Commission, however, that most filings on Form S-8 complied in all material respects with the disclosure requirements of the form and related rules, and that the review process resulted in only minimal disclosure improvement. Under the circumstances, the Commission believed that the public interest would generally best be served by prompt effectiveness of such filings without the delays necessitated by the low review priority given to them. Accordingly, the Commission adopted or amended several rules under the 1933 Act,⁴⁰ as well as Form S-8 itself, to provide for such prompt effectiveness. The net effect of these changes was to permit original filings on Form S-8 to become effective automatically 20 days following the date of filing and to allow post-effective amendments on Form S-8 to become effective automatically on the date of filing.

A second step of even greater significance taken by the Commission was the adoption of a completely revised Form S-8.⁴¹ The new form generally requires fewer disclosures than formerly were necessary, thereby reducing the time and expense involved in preparing such filings. Moreover, as explained in the next section, it provides for a method of updating which requires minimal effort and expense.

B. Changes in Methods of Updating

In order to satisfy the current prospectus requirements of Section 10(a)(3) of the 1933 Act, issuers in the past generally updated their Form S-8 registration statements on an annual basis through the filing of a post-effective amendment. The preparation of

many such amendments was costly and time-consuming, due to the fact that a completely revised prospectus generally had to be included in order to reflect all material changes from the preceding year.

In recognition of the considerable effort and expense involved in preparing annual post-effective amendments, the Commission adopted an updating procedure for the new Form S-8 that is similar to that utilized for many years under Form S-18. The new procedure allows the issuer to incorporate by reference periodic reports required to be filed under the 1934 Act in order to satisfy the majority of all updating requirements.⁴² Under this method, the issuer generally can continue to use the same prospectus (sometimes characterized as an "evergreen prospectus") year-after-year without any fundamental changes. Thus, preparation, printing and distribution costs are considerably reduced when this method is used.

In those unusual situations where annual updating cannot be completely accomplished through the filing of 1934 Act periodic reports,⁴³ the staff has indicated that issuers may utilize an "appendix" to the evergreen prospectus for this purpose.⁴⁴ The appendix generally would consist of a page or two containing the additional information required to update the S-8 and would be distributed to existing plan participants in lieu of a completely revised prospectus. New participants, of course, would be furnished with both the evergreen prospectus and the appendix, and existing participants could also obtain copies of the evergreen prospectus, if they so desired. Again, this method of updating is advantageous because it allows printing and other costs to be reduced.

³⁹ It should be noted that in order to utilize the 1934 Act periodic reports for updating purposes, it is necessary that the accountant for the issuer file a consent with the Commission permitting the financial statements and related accountant's opinion in the issuer's Form 10-K [17 CFR 249.310] to be used in connection with the Form S-8 under the 1933 Act.

⁴⁰ For example, updating by filing a post-effective amendment to the S-8 may still be necessary to disclose: (1) changes in the tax effects which may accrue to employees (and to the issuer) as result of participation in the plan, (2) changes in the approximate number of employees participating in the plan and the number eligible to participate, (3) changes in the names and addresses of the plan administrators and any material relationships between them and the plan participants, the issuer or its affiliates, and (4) changes in the data required for the purpose of evaluating alternative investment media.

⁴¹ Letter re Crocker National Corporation dated September 25, 1980.

C. Other Efforts to Minimize Burdens

In addition to the foregoing, the staff has issued two no-action letters designed to further alleviate the burdens associated with Form S-8.

The first letter⁴⁵ permits issuers to take advantage of the new updating procedure described above without the necessity of making a complete filing on the new Form S-8. The staff's position is based on the fact that the former S-8 form generally required more information to be disclosed than the new form and therefore plan participants will not suffer if the old form continues to be used for a period of time. Thus, an issuer with an existing S-8 registration statement on file generally may avail itself of the new updating procedure immediately by filing a post-effective amendment (using the appendix approach, if desired) containing the information required by Item 12 ("Incorporation of Certain Documents by Reference") and Item 13 ("Additional Information") of the new S-8 form and the undertakings required by Part II of that form.⁴⁶

The second letter⁴⁷ permits issuers to use the summary plan description required by ERISA to satisfy certain of the disclosure requirements of Form S-8 regarding the plan. In effect, this position allows issuers to eliminate essentially duplicative disclosures that may have occurred under ERISA and the 1933 Act in the past. Pursuant to the letter, an issuer is allowed to file the summary plan description as an exhibit to the S-8. The issuer, however, need not attach the summary plan description to the prospectus delivered to employees, since such persons would independently be furnished with a copy of the summary plan description pursuant to the requirements of ERISA.

The staff's position described above is subject to the following conditions: (1) the issuer must state in its Form S-8 prospectus that a current copy of the summary plan description will be provided to any plan participant upon request; (2) the issuer will continue to comply with the requirements of ERISA pertaining to the amendment and distribution of the summary plan description; and (3) the issuer will update, when necessary, the copy of the summary plan description on file with the Commission through the filing of

⁴² *Ameron, Inc.* dated May 1, 1980.

⁴³ Of course, consistent with the updating procedure utilized with respect to Form S-18 filings, the issuer should also file the consent of its independent public accountant, as noted in fn. 42. Further, any material amendments to the plan not previously described in the S-8 would have to be disclosed in the post-effective amendment.

⁴⁴ *Shop & Co., Inc.* dated July 17, 1980.

³⁹ Release 33-6190 (February 22, 1960) [FR 13438].

⁴⁰ The rules involved in the changes were Rules 464 [17 CFR 230.464], 473 [17 CFR 230.473], 475a [17 CFR 230.475a], 477 [17 CFR 230.477], and 485 [17 CFR 230.485].

⁴¹ Release 33-6202 (April 2, 1980) [45 FR 23653]. In that release, the Commission also substantially amended Form 11-K [17 CFR 249.31], the annual report under the 1934 Act required to be filed by plans which have registered interests therein pursuant to the 1933 Act.

exhibits to the S-8 and, where appropriate, the annual reports of the plan filed on Form 11-K.

Accordingly, 17 CFR Part 231, is amended by adding reference to this release thereto.

By the Commission,
George A. Fitzsimmons,
Secretary.

January 15, 1981.

[FR Doc. 81-2857 Filed 1-26-81; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 274

[Docket No. RM81-12]

Interim Rule Under Section 108 of the NGPA Concerning Temporary Pressure Buildup in Qualifying Stripper Wells

Correction

In FR Doc. 81-2203 published in the issue of Thursday January 22, 1981, at page 6901, make the following correction:

On page 6902, third column, under Part 274, the section heading now reading "§ 271.806 * * *" should read "§ 274.206 * * *".

BILLING CODE 1505-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

Redesignation of Hearing Clerk's Office as Dockets Management Branch

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The Food and Drug Administration (FDA) is amending Chapter I of Title 21 of the Code of Federal Regulations to reflect the Hearing Clerk's office name change to Dockets Management Branch.

EFFECTIVE DATE: January 27, 1981.

FOR FURTHER INFORMATION CONTACT:

Agnes B. Black, Federal Register Writer's Office (HFC-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2994.

SUPPLEMENTARY INFORMATION: FDA has designated the Administrative Proceedings Staff-Hearing Clerk's office a branch of the Division of Management Systems and Policy and renamed it the Dockets Management Branch. This

document amends Chapter I of Title 21 of the Code of Federal Regulations to reflect the name change.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 710(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended in Parts 1 through 1299 by changing "office of the Hearing Clerk," "Hearing Clerk's office," and "Hearing Clerk," wherever they appear, to read "Dockets Management Branch."

Effective date: January 27, 1981.

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

Dated: December 23, 1980.

William F. Randolph,

Acting Associate Commissioner, Regulatory Affairs.

[FR Doc. 81-2811 Filed 1-26-81; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Parts 5, 7, 10, 12, 14, 19, 20, 21, 25, 109, 110, 330, 509, 510, 808, 1010, 1030, 1240, and 1250

[Docket No. 80N-0452]

Reorganization/Location Changes

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The Food and Drug Administration is amending the various regulations that were affected by the April 1978 reorganization of the Office of the Commissioner. The amendment includes the transfer of functions between offices, new organizational entities, changes in position and organization titles, and changes in room locations and mailing addresses.

EFFECTIVE DATE: January 27, 1981.

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: 1.

Transfer of functions. The Public Records and Documents Center (PRDC) of the Office of Compliance was abolished, and the Freedom of Information and Privacy Act functions were transferred to the Office of Public Affairs with the administrative proceedings (Hearing Clerk) functions transferring to the retitled Office of Management and Operations. References to PRDC are being changed.

2. *New organizational entities.* A Freedom of Information Staff has been

established in the Office of Public Affairs to perform the Freedom of Information and Privacy Act functions. A Dockets Management Branch has been established in the Office of Management and Operations to perform the administrative proceedings (Hearing Clerk) functions. References to PRDC or Hearing Clerk are being changed according to the division of functions between these two new organizations.

3. *Changes in position and organization titles.* The Associate Commissioner for Compliance became the Associate Commissioner for Regulatory Affairs; the Associate Commissioner for Administration became the Associate Commissioner for Management and Operations; the Assistant Commissioner for Public Affairs became the Associate Commissioner for Public Affairs. The Office of Compliance became the Office of Regulatory Affairs; the Office of Administration became the Office of Management and Operations; the Office of Public Affairs did not change. The Special Assistant for Consumer Affairs now heads a new Office of Consumer Affairs with the title of Associate Commissioner for Consumer Affairs. All references are changed accordingly.

4. *Changes in room locations and mailing addresses.* Wherever appropriate new locations and addresses are referenced.

5. *Other changes.* Because of other reorganizations, references to the Department of Health, Education, and Welfare are changed to the Department of Health and Human Services, and references to the Civil Service Commission are changed to the Office of Personnel Management.

In a rule published elsewhere in this issue of the *Federal Register*, the agency is amending 21 CFR Chapter I, Parts 1 thru 1299, to change the Hearing Clerk's name to Dockets Management Branch.

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 5.1), Chapter I of 21 CFR is amended in Parts 5, 7, 10, 12, 14, 19, 20, 21, 25, 109, 110, 330, 509, 510, 808, 1010, 1030, 1240, and 1250 as follows:

SUBCHAPTER A—GENERAL

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. Part 5 is amended:

a. By revising § 5.105, to read as follows:

§ 5.105 Chief Counsel, Food and Drug Administration.

The Chief Counsel to the Commissioner of Food and Drugs is the Assistant General Counsel, Food and Drug Division, Office of the General Counsel, Department of Health and Human Services, Room 6-57, 5600 Fishers Lane, Rockville, MD 20857.

b. By revising § 5.110, to read as follows:

§ 5.110 FDA Public Information Offices.

(a) *Dockets Management Branch (HFA-305)*. The Dockets Management Branch Public Room is located in Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-443-1753.

(b) *Freedom of Information Staff (HFI-35)*. The Freedom of Information Public Room is located in Room 12A-30, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-443-6310.

(c) *Press Relations Staff (HFI-40)*. Press Offices are located in Room 15B-42, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-443-3285; and in Room 3807, FB-8, 200 C Street SW., Washington, D.C. 20204. Telephone: 202-245-1144.

PART 7—ENFORCEMENT POLICY

2. Part 7 is amended in § 7.42 by revising the introductory text of paragraph (b)(3), to read as follows:

§ 7.42 Recall strategy.

(b) * * *

(3) *Effectiveness checks*. The purpose of effectiveness checks is to verify that all consignees at the recall depth specified by the strategy have received notification about the recall and have taken appropriate action. The method for contacting consignees may be accomplished by personal visits, telephone calls, letters, or a combination thereof. A guide entitled "Methods for Conducting Recall Effectiveness Checks" that describes the use of these different methods is available upon request from the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857. The recalling firm will ordinarily be responsible for conducting effectiveness checks, but the Food and Drug Administration will assist in this task where necessary and appropriate. The recall strategy will specify the method(s) to be used for and the level of effectiveness checks that will be conducted, as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

3. Part 10 is amended:

a. In § 10.3(a) by removing the definition "Hearing Clerk" and adding alphabetically the definition "Dockets Management Branch" to read as follows:

§ 10.3 Definitions.

(a) * * *

"Dockets Management Branch" means the Dockets Management Branch, Office of Management and Operations of the Food and Drug Administration, U.S. Department of Health and Human Services, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

b. In § 10.20 by revising the section heading and paragraph (f), to read as follows:

§ 10.20 Submission of documents to Dockets Management Branch; computation of time; availability for public disclosure.

(f) All submissions are to be mailed or delivered in person to the Dockets Management Branch, Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857, except that a submission which is required to be received by the Branch by a specified date may be delivered in person to the FDA building in Washington (Room 6819, 200 C Street SW., Washington, DC 20204) and will be considered as received by the Branch on the date on which it is delivered.

§ 10.30 [Amended]

c. In § 10.30(b) by revising the entry for the Hearing Clerk to read "Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857."

§ 10.33 [Amended]

d. In § 10.33(b) by revising the entry for the Hearing Clerk to read "Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857."

§ 10.35 [Amended]

e. In § 10.35(b) by revising the entry for the Hearing Clerk to read "Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857."

§ 10.85 [Amended]

f. In § 10.85(b) by revising the entry for the Hearing Clerk to read "Dockets Management Branch, Food and Drug

Administration, Department of Health and Human Services, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857."

g. In § 10.95 by revising paragraphs (b)(2) and (d)(7), to read as follows:

§ 10.95 Participation in outside standard-setting activities.

(b) * * *

(2) Approval forms and all pertinent background information describing the activity will be included in the public file on standard-setting activities established by the Freedom of Information Staff.

(d) * * *

(7) The Commissioner may determine in writing that, because direct involvement by FDA in a particular standard-setting activity is in the public interest and will promote the objectives of the act and the agency, the participation is exempt from the requirements of paragraph (d)(1)(ii) and/or (iii) of this section. This determination will be included in the public file on standard-setting activities established by the Freedom of Information Staff and in any relevant administrative file. The activity may include the establishment and validation of analytical methods for regulatory use, drafting uniform laws and regulations, and the development of recommendations concerning public health and preventive medicine practices by national and international organizations.

h. In § 10.220 by revising paragraph (a), to read as follows:

§ 10.220 Processing of applications by the evaluation board.

(a) Applications shall be processed by an Evaluation Board composed of the Associate Commissioner for Consumer Affairs, or his or her representative, who will serve as chairman of the Evaluation Board, the Associate Commissioner for Management and Operations, or his or her representative, and a third agency employee to be appointed by the Commissioner. Whenever a member of the Evaluation Board is participating in a Part 12, 13, 14, 15, or 16 proceeding, he or she shall be disqualified from reviewing or ruling upon applications for reimbursement filed in connection with that proceeding. In the event of such a disqualification, the disqualified Board member shall be replaced by an agency employee to be appointed by the Commissioner.

**PART 12—FORMAL EVIDENTIARY
PUBLIC HEARING****§ 12.45 [Amended]**

4. In Part 12, § 12.45(a) is amended by revising the entry for the Hearing Clerk to read "Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857."

**PART 14—PUBLIC HEARING BEFORE
A PUBLIC ADVISORY COMMITTEE**

5. In Part 14, § 14.65 is amended by revising paragraph (a), to read as follows:

**§ 14.65 Public inquiries and requests for
advisory committee records.**

(a) Public inquiries on general committee matters, except requests for records, are to be directed to: Committee Management Officer (HFA-306), Office of Management and Operations, Food and Drug Administration, Department of Health and Human Services, 5600 Fishers Lane, Rockville, MD 20857.

**PART 19—STANDARDS OF CONDUCT
AND CONFLICTS OF INTEREST**

6. Part 19 is amended:

a. In § 19.10 by revising paragraphs (a) and (b) and the introductory text of paragraph (d), to read as follows:

**§ 19.10 Food and Drug Administration
Conflict of Interest Review Board.**

(a) The Commissioner shall establish a permanent five-member Conflict of Interest Review Board, which shall review and make recommendations to the Commissioner on all specific or policy matters relating to conflicts of interest arising within the Food and Drug Administration that are forwarded to it by (1) the Associate Commissioner for Management and Operations or (2) anyone who is the subject of an adverse determination by the Associate Commissioner for Management and Operations on any matter arising under the conflict of interest laws, except a determination of an apparent violation of law. The Director, Division of Personnel Management, Office of Management and Operations, shall serve as executive secretary of the Review Board.

(b) It shall be the responsibility of every Food and Drug Administration employee with whom any specific or policy issue relating to conflicts of interest is raised, or who otherwise wishes to have any such matter resolved, to forward the matter to the Associate Commissioner for

Management and Operations for resolution, except that reporting of apparent violations of law are governed by § 19.21.

(d) All decisions relating to specific individuals shall be placed in a public file established for this purpose by the Freedom of Information Staff, e.g., a determination that a consultant may serve on an advisory committee with specific limitations or with public disclosure of stock holdings, except that such determination shall be written in a way that does not identify the individual in the following situations:

b. In § 19.21 by revising paragraph (a), to read as follows:

§ 19.21 Duty to report violations.

(a) The Policy Management Staff, Office of Management and Operations, is responsible for obtaining factual information for the Food and Drug Administration on any matter relating to allegations of misconduct, impropriety, conflict of interest, or other violations of Federal statutes by agency personnel.

PART 20—PUBLIC INFORMATION

7. Part 20 is amended:

a. In § 20.3 by revising paragraph (b), to read as follows:

**§ 20.3 Certification and authentication of
Food and Drug Administration Records.**

(b) A request for certified copies of records or for authentication of records shall be sent in writing to the Freedom of Information Staff (HFI-35), Food and Drug Administration, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857.

b. In § 20.26 by revising paragraph (b), to read as follows:

§ 20.26 Indexes of certain records.

(b) A copy of each such index is available at cost from the Freedom of Information Staff (HFI-35), Food and Drug Administration, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857.

c. In § 20.30 by revising the section heading and paragraph (a), to read as follows:

**§ 20.30 Food and Drug Administration
Freedom of Information Staff.**

(a) The Office responsible for agency compliance with the Freedom of Information Act and this part is:

Freedom of Information Staff (HFI-35), Food and Drug Administration, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857.

d. In § 20.40 by revising paragraphs (a) and (c), to read as follows:

§ 20.40 Filing a request for records.

(a) All requests for Food and Drug Administration records shall be filed in writing by mailing the request or delivering it to the Freedom of Information Staff (HFI-35), Food and Drug Administration, Room 12A-16, 5600 Fishers Lane, Rockville, MD 20857.

(c) Upon receipt of a request for records, the Freedom of Information Staff shall enter it in a public log. The log shall state the date received, the name of the person making the request, the nature of the record requested, the action taken on the request, the date of determination letter sent pursuant to § 20.41(b), and the date(s) any records are subsequently furnished.

e. In § 20.41 by revising paragraph (a), the introductory text of paragraph (b) and paragraph (b)(3)(i), to read as follows:

§ 20.41 Time limitations.

(a) All time limitations prescribed pursuant to this section shall begin as of the time at which a request for records is logged in by the Freedom of Information Staff pursuant to § 20.40(c). An oral request for records shall not begin any time requirement. A written request for records sent elsewhere within the agency shall not begin any time requirement until it is redirected to the Freedom of Information Staff and is logged in there in accordance with § 20.40(c).

(b) Within 10 working days (excepting Saturdays, Sundays, and legal public holidays) after a request for records is logged in at the Freedom of Information Staff, a letter shall be sent to the persons making the request determining whether, or to the extent which, the agency will comply with the request, and, if any records are denied, the reasons therefor.

(3) * * *

(i) The need to search for and collect the requested records from field facilities or other establishments that are separate from the Freedom of Information Staff.

f. In § 20.43 by revising paragraph (b), the introductory text of paragraph (c), and paragraph (c)(2) and (3), to read as follows:

§ 20.43 Waiver of fees.

(b) The Associate Commissioner for Public Affairs may waive payment of

fees when he or she determines, based upon a petition, that the person making the request for records is indigent and that the disclosure has a strong public interest justification. All statements made in any such petition are subject to the False Reports to the Government Act, 18 U.S.C. 1001. A person shall be deemed to be indigent for the purposes of this section if he or she does not have income or resources sufficient to pay the fees involved. Determinations pursuant to this provision will be made within the discretion of the agency.

(c) The Associate Commissioner for Public Affairs may reduce or waive payment of fees when he or she determines, based upon a verified petition, that such reduction or waiver is in the public interest because furnishing the information can be considered primarily as benefiting the general public.

(2) The Associate Commissioner for Public Affairs may make available part of the records requested, or different records from those requested, in response to any such request for waiver of fees where he or she concludes that such records adequately meet that part of the request which is in the public interest.

(3) In making a determination of the broad public interest involved, the Associate Commissioner for Public Affairs will weigh the agency resources involved against the likely benefit to the public.

g. In § 20.44 by revising paragraphs (a) and (f), to read as follows:

§ 20.44 Presubmission review of request for confidentiality of voluntarily submitted data or information.

(a) Any person who is considering submission of data or information voluntarily to the Food and Drug Administration may forward to the Director of the Bureau involved, or to the Associate Commissioner for Regulatory Affairs, a request for presubmission review of the records involved to determine whether the Food and Drug Administration will or will not make part or all of them available for public disclosure upon request if they are submitted. Any such request shall state why the data or information involved fall within an exemption from public disclosure set out in Subpart D of this part and shall enclose the records involved.

(f) A determination based upon a presubmission review pursuant to this section shall be made in writing and

shall be signed only by the Associate Commissioner for Public Affairs.

h. In § 20.47 by revising paragraph (a), to read as follows:

§ 20.47 Denial of a request for records.

(a) A denial of a request for records, in whole or in part, shall be signed by the Associate Commissioner for Public Affairs.

i. In § 20.107 by revising paragraph (a), to read as follows:

§ 20.107 Food and Drug Administration manuals.

(a) All Food and Drug Administration Staff Manuals and instructions to staff that affect a member of the public are available for public disclosure. An index of all such manuals is available at the Food and Drug Administration's Freedom of Information Public Room in accordance with § 20.26.

j. In § 20.108 by revising paragraph (b), to read as follows:

§ 20.108 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.

(b) A permanent file of all such agreements and understandings is available for public review during working hours in the Food and Drug Administration's Freedom of Information Public Room.

k. In § 20.117 by revising the introductory text of paragraph (a), to read as follows:

§ 20.117 New drug information.

(a) The following computer printouts are available for public inspection in the Food and Drug Administration's Freedom of Information Public Room:

PART 21—PROTECTION OF PRIVACY

8. Part 21 is amended:

a. In § 21.1 by revising paragraph (b)(4), to read as follows:

§ 21.1 Scope.

(b) * * *

(4) Apply to personnel records maintained by the Division of Personnel Management, Food and Drug Administration, except as provided in § 21.32. Such records are subject to regulations of the Office of Personnel Management in 5 CFR Parts 293, 294, and 297.

b. In § 21.20 by revising paragraphs (a) and (b)(8), to read as follows:

§ 21.20 Procedures for notice of Food and Drug Administration Privacy Act Record Systems.

(a) The Food and Drug Administration shall issue in the Federal Register on or before August 30 of each year a notice concerning each Privacy Act Record System as defined in § 21.3(c) that is not covered by a notice published by the Department, the Office of Personnel Management, or another agency.

(b) * * *
(8) The notification procedure, i.e., the address of the FDA Privacy Act Coordinator, whom any individual can contact to seek notification whether the system contains a record about him/her.

c. In § 21.32 by revising paragraph (a), the introductory text of paragraph (b)(1), and paragraphs (b)(1)(i), (b)(2), (b)(3)(i) and (ii), (c), (d)(4), (5), and (6), to read as follows:

§ 21.32 Personnel records.

(a) Present and former Food and Drug Administration employees desiring access to personnel records about themselves should consult system notices applicable to the agency's personnel records that are published by the Office of Personnel Management and the Department as well as any notice issued by the Food and Drug Administration.

(b) * * *
(1) The procedures of the Office of Personnel Management at 5 CFR Parts 293, 294, and 297 rather than the procedures in § 21.33 and Subparts D through F of this part, govern systems of personnel records about Food and Drug Administration employees that are subject to notice published by the Office of Personnel Management, i.e., systems that:

(i) The Office of Personnel Management maintains.

(2) The Office of Personnel Management's procedures may, if necessary, be supplemented in the Food and Drug Administration Staff Manual Guide. Current Food and Drug Administration employees should mail or deliver written requests under the Privacy Act for access to personnel records described in this paragraph to the Office of Personnel Management in accordance with 5 CFR 297.106, the Director, Division of Personnel Management (HFA-400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the personnel officer in the servicing HHS Regional Personnel Office. An employee may consult with or direct his or her request to the FDA Privacy Act Coordinator (HFI-30). Requests for access to

personnel records of former employees that are located in Federal Records Centers should be directed to the Office of Personnel Management. Requests under the Privacy Act for amendment of personnel records should be directed to these same officials who are responsible for access to personnel records under this paragraph.

(3) * * *

(i) Refusal to grant access to a record, or refusal to amend a record upon request of an employee, shall only be made by the Associate Commissioner for Management and Operations or his or her designate; and

(ii) Appeals of refusals under paragraph (b)(3)(i) of this section may be made to the Office of Personnel Management in accordance with 5 CFR 297.108(g)(3) and 297.113(b).

(c) Any other Privacy Act Record Systems that contain personnel records, or records that otherwise concern agency employees, that are maintained by offices of the Food and Drug Administration rather than the Division of Personnel Management but which are not subject to the Department's notice for personnel records in operating offices are subject to this part, except that refusals under this part to grant access to or amend records about present or former employees shall be made by the Associate Commissioner for Management and Operations rather than the Associate Commissioner for Public Affairs.

(d) * * *

(4) Records that are subject to this paragraph shall be available for access to an individual, except to the extent that access is refused by the Associate Commissioner for Management and Operations or his or her designate on the grounds that the record is subject to an exemption under § 21.61 or 5 CFR 297.111.

(5) Requests under the Privacy Act for amendment of records subject to this paragraph should be directed to the Director, Division of Personnel Management (HFA-400). Such requests shall be reviewed in accordance with Subpart E of this part. Refusal to amend a record subject to this paragraph (d)(5) shall only be made by the Associate Commissioner for Management and Operations or his or her designate.

(6) Appeals of refusals under paragraph (d)(4) or (5) of this section may be made to the Commissioner of Food and Drugs, except where the Associate Commissioner for Management and Operations or his or her designate indicates with his or her

refusal that the appeal should be made to the Office of Personnel Management.

d. In § 21.40 by revising paragraphs (b) and (g), to read as follows:

§ 21.40 Procedures for submitting requests for notification and access.

(b) An individual desiring notification or access to records shall mail or deliver a request for records in any Food and Drug Administration Privacy Act Records System to the FDA Privacy Act Coordinator (HFI-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(g) The Freedom of Information Staff shall maintain and make available copies of the forms (OF-203 Privacy Act Request forms) to assist individuals in filing requests under § 21.40.

e. In § 21.41 by revising paragraphs (c), (d), (e), (f), and (g), to read as follows:

§ 21.41 Processing of requests.

(c) The FDA Privacy Act Coordinator (HFI-30) in the Freedom of Information Staff shall be responsible for the handling of Privacy Act requests received by the Food and Drug Administration. Requests mailed or delivered to any other office shall be promptly redirected to the FDA Privacy Act Coordinator. Where this procedure would unduly delay the agency's response, however, the agency employee who received the request should consult with the FDA Privacy Act Coordinator and obtain advice as to whether the employee can respond to the request directly.

(d) Upon receipt of a request by the FDA Privacy Act Coordinator, a record shall promptly be made that a request has been received and the date.

(e) A letter in accordance with § 21.42 responding to the request for notification shall issue as promptly as possible after receipt of the request by the Food and Drug Administration. Upon determination by the Freedom of Information Staff that a request for access to records is appropriately treated as a request under Part 20 of this chapter rather than Part 21, or under both parts, the time limitations prescribed in § 21.41 shall apply. In any case, access to available records shall be provided as promptly as possible.

(f) Except as provided in § 21.32, an individual's access to records about him/herself that are retrieved by his/her name or other personal identifiers and contained in any privacy Act Record System may only be denied by the

Associate Commissioner for Public Affairs or his or her designate. An individual shall not be denied access to any record that is otherwise available to him/her under this part except on the grounds that it is exempt under § 21.65(a)(2), that it was compiled in reasonable anticipation of court litigation of formal administrative proceedings, or to the extent that it is exempt or prohibited from disclosure because it includes a trade secret or commercial or financial information that is privileged or confidential information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy of another individual.

(g) The FDA Privacy Act Coordinator shall ensure that records are maintained of the number, status, and disposition of requests under this subpart, including the number of requests for records exempt from access under this subpart and other information required for purposes of the annual report to Congress under the Privacy Act. These temporary administrative management records shall not be considered to be Privacy Act Record Systems. All records required to be kept under this paragraph shall only include requesting individuals' names or personal identifiers for so long as any request for notification, access, or amendment is pending. The identity of individuals making request under this subpart shall be regarded as confidential and shall not be disclosed under Part 20 of this chapter (the public information regulations) to any other person or agency except as is necessary for the processing of requests under this subpart.

f. In § 21.42 by revising paragraph (b), to read as follows:

§ 21.42 Responses to requests.

(b) Except as provided in § 21.32, access to a record may only be denied by the Associate Commissioner for Public Affairs or his or her designate. If access to any record is denied wholly or in substantial part, the letter shall state the right of the individual to appeal to the Commissioner of Food and Drugs.

g. In § 21.43 by revising paragraph (a)(2), to read as follows:

§ 21.43 Access to requested records.

(a) * * *
(2) Permitting the requesting individual to review the records in person between 9 a.m. and 4 p.m. at the office of the FDA Privacy Act Coordinator, at the Freedom of Information Staff Public Room at the address shown in § 20.30 of this chapter.

or at any Food and Drug Administration field office listed in § 5.115 of this chapter or at another location or time upon which the Food and Drug Administration and the individual agree. Arrangement for such review can be made by consultation between the FDA Privacy Act Coordinator and the individual. An individual seeking to review records in person shall generally be permitted access to the file copy, except that where the records include nondisclosable information, a copy shall be made of that portion of the records, with the nondisclosable information blocked out. Where the individual is not given a copy of the record to retain, no charge shall be made for the cost of copying a record to make it available to an individual who reviews a record in person under this paragraph.

h. In § 21.50 by revising paragraph (c), to read as follows:

§ 21.50 Procedures for submitting requests for amendment of records.

(c) Requests to amend records shall be submitted, in writing, to the FDA Privacy Act Coordinator in accordance with § 21.40(b). Such requests shall include information sufficient to enable the Food and Drug Administration to locate the record, a brief description of the items of information requested to be amended, and the reasons why the record should be amended together with any appropriate documentation or arguments in support of the requested amendment. An edited copy of the record showing the described amendment may be included. Verification of identity should be provided in accordance with § 21.44.

i. In § 21.51 by revising paragraph (a)(2), to read as follows:

§ 21.51 Responses to requests for amendment of records.

(a) * * *

(2) Inform the individual of its refusal to amend any portion of the record in the manner requested, the reason for the refusal, and the opportunity for administrative appeal to the Commissioner of Food and Drugs. Except as provided in § 21.32, such refusal may only be issued by the Associate Commissioner for Public Affairs or his or her designate.

j. In § 21.61 by revising paragraph (b)(1), (2), (3), and (4), to read as follows:

§ 21.61 Exempt systems.

(b) * * *

(1) Bio-research monitoring Information System—HHS/FDA/BD/09-10-0010.

(2) Regulated Industry Employee Enforcement Records—HHS/FDA/ACMO/09-10-0002.

(3) Employee Conduct Investigative Records—HHS/FDA/ACMO/09-10-0013.

(4) Service Contractor Employee Investigative Records—HHS/FDA/ACMO/09-10-0014.

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

9. Part 25 is amended:

a. In § 25.25 by revising paragraph (a)(3)(v), to read as follows:

§ 25.25 Preparation and review procedures.

(a) * * *

(3) * * *

(v) All comments on draft environmental impact statements shall be submitted in quintuplicate to the Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, where they shall be available for public inspection during working hours, Monday through Friday.

b. In § 25.30 by revising paragraph (a), to read as follows:

§ 25.30 Public availability of environmental impact statements.

(a) All draft and final environmental impact statements, all environmental impact analysis reports, if required, and all environmental assessment reports, if required, except for such impact statements, reports, or assessments on investigational new drugs or investigational new animal drugs that are confidential information under Part 20 of this chapter, shall be available for public inspection through the Dockets Management Branch.

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

PART 109—UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL

10. Part 109 is amended in § 109.30 by revising paragraph (b), to read as follows:

§ 109.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

* * *

(b) A compilation entitled "Analytical Methodology for Polychlorinated Biphenyls, February 1973" for determining compliance with the tolerances established in this section is available from the Dockets Management Branch, Department of Health and Human Services, Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

PART 110—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING HUMAN FOOD

11. Part 110 is amended § 110.99 by revising paragraph (e), to read as follows:

§ 110.99 Natural or unavoidable defects in food for human use that present no health hazard.

(e) Current action levels for natural and unavoidable defects in food for human use that present no health hazard are as follows. (Levels that have been adopted on a temporary basis prior to publication as a regulation may be obtained upon request at the Office of Public Affairs, Food and Drug Administration, Room 15B-42, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.)

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

12. Part 330 is amended:

a. In § 330.1 by revising paragraph (g), to read as follows:

§ 330.1 General conditions for general recognition as safe, effective, and not misbranded.

(g) The labeling for all drugs contains the general warning: "Keep this and all drugs out of the reach of children." The labeling of drugs used for oral administration shall also state: "In case of accidental overdose, seek professional assistance or contact a poison control center immediately." The labeling for drugs administered rectally or used topically shall state: "In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately." The Food and Drug Administration will grant an exemption from these general warnings where appropriate upon petition, which shall be maintained in a permanent file for public review by the Dockets

Management Branch, Food and Drug Administration, Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

b. In § 330.10 by revising paragraph (a)(13)(iii) and (iv), to read as follows:

§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

(a) * * *

(13) * * *

(iii) Such notification shall be in the form of a Category III Notification Statement and shall be submitted in quintuplicate to the Dockets Management Branch, Food and Drug Administration, Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. A Category III Notification Statement shall contain: (a) Name and address of the sponsor of the study, (b) name and address of each person directly responsible for monitoring the study, (c) each Category III condition being tested in the manner suggested in the applicable final regulation for that class of drugs, and (d) the anticipated date that testing will be initiated, which shall be prior to the date after which a product with a condition subject to paragraph (a)(6)(ii) (Category II) of this section may no longer be shipped in interstate commerce.

(iv) A copy of each Category III Notification Statement shall be maintained in a permanent file for public review in the Dockets Management Branch, Food and Drug Administration, Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Upon written request or notice in the Federal Register, the manufacturer or distributor shall furnish to the Food and Drug Administration evidence of the type of test being performed (e.g., in vitro, animal, human, survey, or other), and/or other information and data appropriate to the testing being conducted.

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 509—UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL

13. Part 509 is amended in § 509.30 by revising paragraph (b), to read as follows:

§ 509.30 Temporary tolerances for polychlorinated biphenyls (PCB's).

(b) A compilation entitled "Analytical Methodology for Polychlorinated

Biphenyls, February 1973" for determining compliance with the tolerances established in this section is available from the Dockets Management Branch, Food and Drug Administration, Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

PART 510—NEW ANIMAL DRUGS

14. Part 510 is amended in § 510.112 by revising paragraph (a), to read as follows:

§ 510.112 Antibiotics used in veterinary medicine and for nonmedical purposes; required data.

(a) An ad hoc committee, Committee on the Veterinary Medical and Nonmedical Uses of Antibiotics, was formed by the Food and Drug Administration to study, and advise the Commissioner on, the use of antibiotics in veterinary medicine and for various nonmedical purposes as such uses may affect the enforcement of the Federal Food, Drug, and Cosmetic Act with respect to the safety and effectiveness of such substances. A copy of the report may be obtained from the Food and Drug Administration, Office of Public Affairs, Room 15B-42, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

SUBCHAPTER H—MEDICAL DEVICES

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

15. Part 808 is amended in § 808.20 by revising paragraph (b), to read as follows:

§ 808.20 Application.

(b) An application for exemption shall be in the form of a letter to the Commissioner of Food and Drugs and shall be signed by an individual who is authorized to request the exemption on behalf of the State or political subdivision. Four copies of the letter and any accompanying material, as well as any subsequent reports or correspondence concerning an application, shall be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. The outside wrapper of any application, report, or correspondence should indicate that it concerns an application

for exemption from preemption of device requirements.

SUBCHAPTER J—RADIOLOGICAL HEALTH

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

16. Part 1010 is amended:

a. In § 1010.4 by revising the introductory text of paragraph (b), to read as follows:

§ 1010.4 Variances.

(b) Applications for variances. Applications for variances or for amendments or extensions thereof shall be submitted in quintuplicate to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

b. In § 1010.5 by revising the introductory text of paragraph (c), to read as follows:

§ 1010.5 Exemptions for products intended for United States Government use.

(c) Application for exemption. An application for exemption, or for amendment or extension thereof, shall be submitted in quintuplicate to the Dockets Management Branch, Food and Drug Administration, Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. For an exemption pursuant to the criteria prescribed in paragraph (a)(1) of this section, the application shall include the information prescribed in paragraph (c)(1) through (13) of this section. For an exemption pursuant to the criteria prescribed in paragraph (a)(2) of this section, the application shall include the information prescribed in paragraph (c)(3) through (13) of this section. An application for exemption, or for amendment or extension thereof, and correspondence relating to such application shall be made available for public disclosure in the Dockets Management Branch except for confidential or proprietary information submitted in accordance with Part 20 of this chapter. Information classified for reasons of national security shall not be included in the application. Except as indicated above, the application for exemption shall include the following:

PART 1030—PERFORMANCE STANDARDS FOR MICROWAVE AND RADIO FREQUENCY EMITTING PRODUCTS

17. Part 1030 is amended in § 1030.10 by revising the introductory text of paragraph (c)(6)(iv), to read as follows:

§ 1030.10 Microwave ovens.

(c) * * *

(6) * * *

(iv) Upon application by a manufacturer, the Director, Bureau of Radiological Health, Food and Drug Administration, may grant an exemption from one or more of the statements (radiation safety warnings) specified in paragraph (c)(6)(i) of this section. Such exemption shall be based upon a determination by the Director that the microwave oven model for which the exemption is sought should continue to comply with paragraph (c) (1), (2), and (3) of this section under the adverse condition of use addressed by such precautionary statement(s). Applications shall be submitted in quintuplicate to the Dockets Management Branch, Food and Drug Administration, Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Copies of the written portion of the application, including supporting data and information, and the Director's action on the application will be maintained by the Branch for public review. The application shall include:

SUBCHAPTER L—REGULATIONS UNDER CERTAIN OTHER ACTS ADMINISTERED BY THE FOOD AND DRUG ADMINISTRATION

PART 1240—CONTROL OF COMMUNICABLE DISEASES

18. Part 1240 is amended in § 1240.62 by revising paragraph (e), to read as follows:

§ 1240.62 Turtles.

(e) *Petitions.* The Commissioner of Food and Drugs, either on his own initiative or on behalf of any interested person who has submitted a petition, may publish a proposal to amend this regulation. Any such petition shall include an adequate factual basis to support the petition, and will be published for comment if it contains reasonable grounds for the proposed regulation. A petition requesting such a regulation, which would amend this regulation, shall be submitted to the Dockets Management Branch, Food and Drug Administration, Room 4-62,

Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

PART 1250—INTERSTATE CONVEYANCE SANITATION

19. Part 1250 is amended in § 1250.51 by revising paragraph (f)(4)(ii), to read as follows:

§ 1250.51 Railroad conveyances; discharge of wastes.

(f) * * *

(4) * * *

(ii) A public file of requested variances and extensions, their disposition, and information relating to pending actions will be maintained in the Dockets Management Branch, Room 4-62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FDA finds that notice, public procedure, and delayed effective date are unnecessary for the issuance of these amendments because they are nomenclature changes that do not impose an additional duty or burden on any person but rather clarify an existing regulation.

Effective date. This regulation shall become effective January 27, 1981.

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

Dated: December 23, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-2812 Filed 1-26-81; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 74

[Docket No. 77C-0276]

D&C Orange No. 4; Listing of Color Additives Subject to Certification

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is revising the specifications for D&C Orange No. 4 for use in externally applied drugs and cosmetics. This action is being taken because a tolerance for 4,4'-(diazamino)-dibenzenesulfonic acid was inadvertently omitted in specifications for D&C Orange No. 4.

DATE: Effective February 27, 1981.

Objections by February 26, 1981.

ADDRESS: Written objections may be sent to the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Andrew D. Laumbach, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 28, 1979 (44 FR 50360), FDA proposed to amend the specifications for D&C Orange No. 4 by adding a tolerance for 4,4'-(diazamino)-dibenzenesulfonic acid. The revision, proposed at FDA's own initiative, was necessary because a tolerance for 4,4'-(diazamino)-dibenzenesulfonic acid was inadvertently omitted in the regulation for D&C Orange No. 4 under §§ 74.1254 and 74.2254 (21 CFR 74.1254 and 74.2254). No comment was received in response to the proposal.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706(b), (c), and (d), 74 Stat. 399-403 as amended (21 U.S.C. 376(b), (c), and (d))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 74 is amended in § 74.1254 by inserting, after the entry for "Subsidiary colors" in the specifications in paragraph (b), a new entry to read as follows:

§ 74.1254 D&C Orange No. 4.

(b) * * * 4,4'-(Diazamino)-dibenzenesulfonic acid, not more than 0.1 percent.

Any person who will be adversely affected by the foregoing order may at any time on or before February 26, 1981 file with the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written objections to this order. Objections shall show how the person filing will be adversely affected by the order, specify with particularity the provisions of the order deemed objectionable, and state the grounds for the objections. Objections shall be filed in accordance with the requirements of § 71.30 (21 CFR 71.30). If a hearing is requested, the objections shall state the issues 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 if a hearing is held. Four copies of all documents shall be filed and should be identified with the docket number found in brackets in the heading of this document. Received objections may be seen in the Dockets Management Branch, from 9 a.m. to 4 p.m., Monday through Friday.

Effective date. This regulation shall be effective February 27, 1981 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.

(Sec. 706(b), (c), and (d), 74 Stat. 399-403 as amended (21 U.S.C. 376(b), (c), and (d)))

Dated: January 19, 1981.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

(FR Doc. 2017- Filed 1-26-81; 8:45 am)

BILLING CODE 4110-03-M

21 CFR Part 146

[Docket No. 78N-0236]

Grapefruit Juice; Standards of Identity and Fill of Container

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing standards of identity and fill of container for grapefruit juice. These standards were developed after considering the Codex Alimentarius Commission's "Recommended International Standard for Grapefruit Juice Preserved Exclusively by Physical Means," the U.S. Department of Agriculture's "United States Standards for Grades of Grapefruit Juice," and the comments received in response to the proposal. The purpose of this action is to promote honesty and fair dealing in the interest of consumers and facilitate international trade.

DATES: Effective July 1, 1983, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date. Voluntary compliance may begin February 27, 1981. Objections by February 26, 1981.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305) (formerly the Hearing Clerk's office), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: F. Leo Kauffman, Bureau of Foods (HFF-214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1164.

SUPPLEMENTARY INFORMATION: The standards established by this final rule will, among other things, (1) provide for the addition of concentrated grapefruit juice to grapefruit juice in an amount not to exceed 15 percent of the grapefruit juice soluble solids; (2) permit the adjustment of grapefruit pulp, grapefruit oil, and grapefruit essence content

(components derived from grapefruit) in accordance with good manufacturing practice; (3) permit the addition of specified dry nutritive carbohydrate sweeteners to grapefruit juice; (4) establish a minimum grapefruit juice soluble solids requirement of 9 percent by weight for the product "grapefruit juice from concentrate"; (5) permit the use of specified liquid or dry sweeteners when concentrated juice is used in the preparation of "grapefruit juice from concentrate"; (6) establish a standard of fill of container based upon a minimum of 90 percent of the total capacity of the container except when the food is frozen; and (7) employ a statistical sampling plan for determining compliance with fill-of-container requirements.

A proposal to establish standards of identity and fill of container for grapefruit juice was published in the Federal Register of December 15, 1978 (43 FR 58575). The proposal invited interested persons to submit comments with supporting data concerning: (1) the benefit of including a provision permitting the addition of concentrated grapefruit juice to grapefruit juice; (2) the limitation that should be placed on the amount of concentrate which may be added to grapefruit juice as well as the type of labeling that would be appropriate to inform the consumer of such addition; (3) the quantity (limitation on the amount) of sweetener that may be added to the juice. The proposal also invited the submission of any available data in support of a specific maximum of the grapefruit oil and/or grapefruit essence content.

Nine letters, each containing one or more comments, were received from one government agency, three trade associations representing grapefruit juice packers, four processors or packers, and one supplier of sweeteners. The comments and the agency's responses are as follows:

"Fresh" Grapefruit Juice

1. Three comments suggested that a separate standard of identity for "fresh" grapefruit juice should be established.

The agency disagrees. No data were submitted, nor is the agency aware of any data that support the establishment of a separate standard of identity for "fresh" grapefruit juice. Therefore, without the evidence to demonstrate otherwise, FDA concludes that a regulation covering this product is unnecessary. This is in keeping with the President's directive not to promulgate needless regulations. Any interested person who believes that a separate standard for "fresh" grapefruit juice is

necessary is invited to submit a petition with supporting data that demonstrate this need.

Preparation for Canning—Centrifuging

2. Two comments recommended that the words "which may include centrifuging" under § 146.132(a)(1) (21 CFR 146.132(a)(1)) be deleted. They contended that listing of one type of permitted mechanical extraction could otherwise be interpreted to imply that certain other unlisted types of mechanical extraction will not be permitted.

FDA agrees, and § 146.132(a)(1), as set out below, reflects this change.

Filtering

3. Two comments recommend that the words "but not filtering" under § 146.132(a)(1) be deleted. They argued that (1) filtering could be interpreted to refer to finishing which is essential to the separation of the juice from rag, seed, and excess pulp and (2) there is, in their opinion, no known reason for prohibiting filtering.

FDA agrees that there may be instances where processors may wish to use filtering in the finishing processes. Therefore, § 146.132(a)(1), as set out below, reflects this change.

Grapefruit Components vs. Optional Ingredients

4. Two comments recommended that § 146.132(a)(1) should be reworded to include a provision for "grapefruit components," i.e., grapefruit pulp, oil, and essence, to distinguish them from food ingredients (e.g., sugar). Further, the comments stated that inherent grapefruit components derived from grapefruit should not be considered to be "ingredients" and, therefore, should not be declared. In order to accomplish that purpose, the comments recommended that the words "grapefruit components" be added to distinguish pulp, oil, and essence from optional ingredients.

FDA agrees that the grapefruit components need not be declared as optional ingredients and should be distinguished from optional ingredients, and § 146.132(a)(1), as set out below, reflects this change. Further § 146.132(a)(2) lists the optional ingredients permitted as discussed below under the heading "Optional Ingredients."

Pulp, Oil, and Essence

5. Two comments contended that the proposal allowed for the removal of pulp, but failed to allow for its restoration. The comments also suggested that the use of the word