information needed by the federal government for program administration.

(3) At least 30 days before the transfer is to occur, EPA must publish notice of the transfer in the **Federal Register**; in enough of the largest newspapers in the state to attract statewide attention; and to persons on appropriate state mailing lists.

(b) When EPA begins proceedings to determine whether to withdraw approval of a state program (either on its own initiative or in response to a petition from an interested person), withdrawal proceedings must be conducted in accordance with procedures set out in 40 CFR 271.23 (b) and (c), except for § 271.23(b)(8)(iii) to the extent that it deviates from requirements under § 281.60.

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September 23, 1988

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 801

Medical Devices; Labeling; User Labeling for Menstrual Tampons; Proposed Ranges of Absorbency for Menstrual Tampons; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 86N-0479]

Medical Devices; Labeling; User Labeling for Menstrual Tampons; Proposed Ranges of Absorbency for Menstrual Tampons

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to require that manufacturers of menstrual tampons add to each tampon package label a letter designation of the range of absorbency of the products. The purpose of the proposed rule is to enable consumers to compare the absorbency of one brand and style of tampons with the absorbency of other brands and styles.

Labeling of tampons to allow consumers to compare the absorbency of different brands and styles is important because the use of tampons is associated with toxic shock syndrome (TSS), a rare but sometimes fatal disease, and the risk of contracting TSS increases with the use of tampons of higher absorbency. FDA is proposing this rule under the Federal Food, Drug, and Cosmetic Act.

FDA is also announcing the availability of, and requesting comments on, a citizen petition submitted by the Public Citizen Health Research Group (HRG) concerning absorbency labeling for tampons.

DATE: Comments on the proposed rule and on HRG's petition by December 22, 1988. FDA is proposing that any final rule based on this proposal take effect for packages of tampons initially introduced or initially delivered for introduction into commerce 6 months after its date of publication in the **Federal Register.**

ADDRESS: Written comments to the Dockets Management Branch (HFA-305),Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Les Weinstein, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION:

A. Toxic Shock Syndrome (TSS)

TSS is a rare but serious and sometimes fatal disease that occurs most often in menstruating women 30 years of age or younger who use tampons, although it can occur in any person of any age (Ref. 6). TSS is believed to be caused by a bacterium, *Staphylococcus aureus,* that produces a toxin or toxins (Ref. 6). TSS is characterized by a rapid drop in blood pressure and shock. The warning signs of TSS include a sudden fever (usually 102 °F or more), vomiting, diarrhea, fainting, near fainting or dizziness when standing, a sunburn-like rash, and shedding of the skin of the palms of the hands and soles of the feet 1 or 2 weeks after onset of the illness.

In the **Federal Register** of June 22, 1982 (47 FR 26982), FDA published a final rule to require manufacturers of tampons to include information about TSS in the labeling of the devices (21 CFR 801.430). FDA stated in the preamble to that rule that a reasonable estimate of the incidence of TSS is between 6 and 17 per 100,000 menstruating girls and women per year (47 FR 26982), and that women 30 and under and teenage girls are at greater risk of contracting TSS (47 FR 26986). The actual incidence of TSS remains unknown, primarily because of the lack of an ongoing active TSS reporting system. In 1980, the Centers for Disease Control (CDC) initiated the national TSS surveillance system (predominantly a passive reporting system) and CDC tabulates all cases that are reported. CDC advises that, from a peak of about 120 reported cases in 1 month in 1980 (Ref. 1), the numbers of new reported TSS cases have leveled off and are now reported at a national rate of approximately 14 cases per month (Ref. 37). CDC estimated that its passive surveillance system detects approximately 15 percent of the TSS cases that actually occur (Ref. 1). Thirty-nine deaths from TSS have been reported to FDA's medical device reporting (MDR) system during the period December 1984 through May 1987 (Ref. 45).

Several epidemiologic studies have demonstrated that there is a statistically significant association between tampon use and the occurrence of TSS. These studies were conducted by CDC (Refs. 1 and 2), the Utah State health department (Ref. 3), the Wisconsin State health department (Ref. 4), and the Minnesota, Wisconsin, and Iowa State health departments (the Tri-State study) (Refs. 5, 7, and 8). Based upon an evaluation of the risk factors associated with TSS, the Tri-State study also concluded that use of high absorbency tampons increased the risk of contracting TSS. This conclusion was supported by the Institute of Medicine of the National Academy of Sciences, which reviewed all the unavailable scientific data on TSS in 1981 (Ref. 6).

The association between TSS and tampon absorbency is an important finding of the Tri-State study. The finding was based on a subset of patients who each used exclusively one tampon brand, and within that brand, one style. Fifty-four patients (out of a total of 80 in the study) and 104 controls (out of a total of 160 in the study) were in that subset of patients. Several statistical analyses were performed on the data, permitting a calculation of the likely relative risk of TSS posed by tampons of different absorbencies within the same brand. The results of the analyses can be represented by the relative risk of TSS for each of four tampon absorbencies, set out below in terms of mean absorbency (fluid capacity) in grams (Ref. 5).

Group	Absorbency	
	Mean fluid capacity in grams*	Relative risk of TSS
1	19.11	8.84
2	16.09	6.26
3	12.91	4.36
4	10.30	3.24

*The absorbencies are those of tampons as manufactured at the time of the study; the absorbencies of specific products may have changed (lowered or raised) since then.

In summary, the Tri-State study (Ref. 5) confirmed the one finding consistent among all TSS epidemiologic studies: tampon use is associated with TSS. In addition, the Tri-State study demonstrated that there is an association between the level of tampon absorbency and TSS. Moreover, based on its assessment of all the current

information respecting TSS, the Institute of Medicine of the National Academy of Sciences, through its Committee on TSS, recommended that use of high absorbency tampons be minimized (Ref. 6).

The conclusions in a recent report (Ref. 46) of a study of the relationship of tampon use to cases of TSS conducted by CDC fully support the Tri-State study's conclusions regarding the role of tampon absorbency in TSS risk. The CDC study includes cases of TSS with onset between January 1, 1983, and December 31, 1984, and compares the data of 285 tampon-associated cases of TSS where the woman reported using a single brand of tampon, to age- and year-matched controls from a national survey of tampon usage. CDC found that users of all brands of tampons have elevated "odds ratios" (a measure of relative risk) for TSS compared to nonusers of tampons. Based on an analysis of the 215 cases in which the users gave information as to the absorbency of tampon used, CDC also found that the relative risk of TSS generally increases as the absorbency of the tampon increases and that without regard to the chemical composition of the tampon, for each gram increased in absorbency, there is a significant increase in the risk of illness (Refs. 46 and 47). This finding is valid over the entire range of absorbencies represented by each category of chemical composition, which indicates that use of a low absorbency tampon is likely to reduce the risk of TSS.

To provide a perspective on the overall risk of contracting TSS, the CDC report describes one study stating that the estimated incidence of TSS is between 2 and 4 cases per 100,000 menstruating girls and women per year. These incidence data are based on data from one study from a limited geographical area, northern California, and should be considered as a subset of the overall national incidence data. There is currently no explanation for this reported lower incidence of TSS. It is possible, however, that earlier reports of higher incidences were based on data from time periods in which higher absorbency tampons and higher risk tampons were widely used (Ref. 47).

In the years since the initial research on and evaluation of TSS were done, TSS epidemiologic data have been reevaluated and critiqued. Concerns have been raised regarding the validity of the results owing to possible bias in the reporting of data to the investigators. In 1982, the Journal of the American Medical Association (JAMA) published an article describing biases that, taken together, could allegedly reproduce the association between tampon use and TSS (Ref. 9), albeit artificially. Because of that possibility, the authors of the 1982 JAMA article questioned the conclusion that there was an association between tampon use and TSS. However, in an editorial response accompanying the article, B. S. Hulka (a member of the Institute of Medicine Committee on TSS) expressed a contrary view (Ref. 11). The editorial used the Tri-State study data to demonstrate that a large error in reporting tampon use versus nonuse would have been necessary to invalidate the data establishing an association between tampons and TSS. Because of the great amount of careful surveillance actually done at the time of the Tri-State study, FDA concludes that such a large error was not a reasonable possibility.

A 1984 study published in the American Journal of Medicine (Ref. 10) expressed an additional concern regarding the validity of the Tri-State study results. The 1984 study tested how physicians' diagnostic judgments were influenced by knowledge of a patient's gender, menstrual history, or menstrual product use based on the premise that physician bias in recognizing TSS could influence the basis tampon/TSS association data. The study concluded that there was a bias towards diagnosing TSS in tampon users. The 1984 study, however, involved physicians diagnosing TSS after several years of publicity about the reported association. It did not demonstrate that physicians who diagnosed TSS cases that were included in epidemiologic case control studies conducted in 1980 were influenced in making a TSS diagnosis by a patient's use of tampons. In both CDC's first study (Ref. 1) and the Wisconsin State health department study (Ref. 4), the researchers closed case-admission before the appearance of national news media coverage linking TSS with tampon use.

FDA continues to believe that substantial scientifically sound evidence shows that there is an association between the use of tampons and TSS and that increased absorbency is associated with increased risk. The consensus of the scientific community is that women who choose to use tampons should use tampons with the minimum absorbency needed to control menstrual flow in order to reduce their risk of contracting TSS.

B. Current Special Labeling Requirements for Menstrual Tampons

Based on the evidence of the increased risk of TSS associated with the use of tampons, particularly by young women and girls, the severity and rapid onset of the disease, and the significant risk of death for users who contract TSS, FDA concluded that failure to inform consumers about TSS constituted an omission of material facts about tampons (47 FR 26983). Accordingly, in the **Federal Register** of June 22, 1982 (47 FR 26982), FDA established 21 CFR 801.430 to require manufacturers of menstrual tampons to include certain information about TSS in the labeling of the devices. Section 801.430 allows a manufacturer to provide the TSS information only in the package insert if the following alert appears prominently and legibly on the package label:

> ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.

The TSS information required by the regulations must be placed prominently and legibly in a package insert or on the package of menstrual tampons in terms understandable to the layperson and must include the following:

1. Warning signs of TSS and what to do if these or other signs appear;

2. The risk of TSS of all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated incidence of TSS, and the risk of death from contracting TSS;

3. The advisability of using tampons with the minimum absorbency needed to control menstrual flow;

4. How to avoid the risk of getting tampon-associated TSS by not using tampons, and possibly reduce the risk of getting TSS by alternating tampon use with sanitary napkin use; and

5. The need to seek medical attention before again using tampons if TSS warning signs have occured in the past, or if women have any questions about TSS or tampon use.

As discussed in the following sections of this preamble, FDA believes that § 801.430 does not ensure that women are provided with the information they need to select the lowest absorbency needed to control menstrual flow and thus, to reduce the risk of contracting TSS. Moreover, tampon manufacturers have been unable to agree to provide, on a voluntary basis, absorbency information that would facilitate interbrand comparisons of products. For these reasons, FDA is now proposing to amend § 801.430, as described in detail in Section K of this preamble, to require

that manufacturers provided additional absorbency information.

C. TSS Education

The agency continues to provide information to the public about TSS through public statements and professional, consumer, and industry education programs. Although FDA informs the general public about TSS because it can strike anyone, not just tampon users, FDA is especially concerned about the prospective or new tampon user who may not read tampon labeling information or understand its significance. In an effort to reduce the severity and the incidence of TSS in this group, FDA conducted a nationwide poster education program designed to educate teenage girls about TSS, its symptoms, and what to do should the symptoms occur. Because younger women and teenage girls are at the greatest risk of contracting TSS and have little or no experience upon which to draw in evaluating the absorbency of different tampon brands and styles, they could benefit the most from absorbency information on the labeling of tampons.

D. Menstrual Tampon Absorbency Claims

In June 1983, FDA's Center for Devices and Radiological Health sent a letter (Ref. 13) to all manufacturers of tampons regarding absorbency claims on tampon packaging. The letter noted that some tampon packages featured advertising or promotional material that stressed absorbency and that this emphasis was at variance with advice to use the minimum absorbency needed to control menstrual flow. The agency requested that all manufacturers add to the outside package label of tampons the advice to use the minimum absorbency needed to control menstrual flow and to place this advice next to the promotional messages about absorbency. Because all manufacturers complied voluntarily with this request, FDA believes that they recognize the public health value of the advice to use the minimum absorbency needed.

E. American Society for Testing and Materials' Effort to Develop a Standard

On July 13, 1981, FDA asked the chairperson of the American Society for Testing and Materials (ASTM) Committee on Medical and Surgical Materials and Devices (the committee) to form a task force to develop a standard for tampons (Ref. 14). FDA believed that the private sector was interested in developing a standard that would address concerns regarding absorbency and that the appropriate forum in which to develop such a standard would be ASTM. The agency suggested that the standard include a method for determining tampon absorbency and provide for appropriate labeling.

In response to FDA's request, the committee first met with representatives from consumer groups, industry, and FDA in November 1981. The committee agreed to set up a task force to develop a voluntary standard for tampons. The task force, formally established in January 1982, was composed of representatives from the following organizations: Coalition for Medical Rights of Woman; Women Health International; National Consumers League; National Women's Health Network; Boston Women's Health Book Collective; Empire State Consumer Association, Inc.; Personal Products; International Playtex, Inc.; Kimberly-Clark Corp.; Jeffrey-Martin, Inc.; Tambrands, Inc. (formerly Tampax); Sentinel Consumer Products, Inc.; and FDA. The task force made a commitment to develop, among other things, a standard test method for measuring tampon absorbency and a means for expressing absorbency on tampon labeling.

F. Public Citizen Health Research Group Petitions

1. The July 29, 1982, Petition

On July 29, 1982, the Public Citizen Health Research Group (HRG) petitioned FDA to establish a performance standard for tampons that would (1) prescribe a test method for determining tampon absorbency; (2) require tampon manufacturers to determine the absorbency of each of their styles of tampons using the test method adapted by the ASTM task force (the Syngyna (simulated vagina) test); (3) establish a uniform nomenclature for tampon absorbency; and (4) compel manufacturers to disclose absorbency on the outside of the tampon packages.

On September 22, 1982, FDA issued a tentative response (Ref. 19) to HRG's petition. The agency stated that, although it agreed in substance with the objectives of the petition, FDA preferred to work actively with the ASTM tampon task force because the agency believed that the voluntary standards process was the most efficient and economical method available for developing uniform tampon absorbency testing and labeling. FDA also pointed out that scientific data regarding the relationship of absorbency to the risk of TSS were limited. The agency promised that it would monitor the task force's progress, and indicated that the agency would reconsider its position if it became evident that the task force's efforts were being delayed or were not adequately addressing the issues of absorbency and disclosure.

On November 2, 1982, HRG submitted a supplement to its petition (Ref. 20), which stated that HRG considered tampons to be misbranded within the meaning of section 502(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(a)). HRG reiterated its request that FDA establish a performance standard for tampons.

On April 22, 1983, FDA issued a final response denying HRG's petition as supplemented (Ref. 21). As FDA had stated in its September 22, 1982, tentative response to HRG, the agency continued to agree in substance with the objectives of the petition but preferred to work with the ASTM task force instead of initiating regulatory action or rulemaking. However, FDA also advised HRG that, if regulatory action or rulemaking became necessary or if the task force's activities became delayed and the public health was apparently being compromised, FDA would reconsider its position.

2. The August 20, 1987, Petition

On August 20, 1987, FDA received another citizen petition (87P-0280CP) from HRG concerning absorbency labeling of tampons. FDA is announcing the availability of this petition and invites interested persons to submit written comments on it. Two copies of any comments are to be submitted by December 22, 1988, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In its August 20, 1987, petition, HRG requests that FDA:

1. Issue a rule on an expedited basis that would:

a. Eliminate the unstandardized nomenclature ("junior," "regular," "super," "super plus") used by tampon manufacturers to describe absorbency.

b. Require tampon manufacturers to determine the fluid capacity of each style of tampon they manufacture using the "syngyna test," which simulates tampon use conditions in humans. Require manufacturers to test, and periodically retest, a statistically significant number of tampons to assure that fluid capacity measurement is accurate.

c. Require tampon manufacturers to assign a single number to absorbency based on syngyna test results. For example, currently marketed tampons will yield syngyna test results ranging from 5 to 18 grams of absorbed liquid. Absorbency factors on tampon packages would range from 5 to 18,

where 5 would signify the least absorbent brand and 18 the most absorbent.

d. Require tampon manufacturers to disclose these numerical absorbency factors on the outside of tampon boxes in a uniform fashion, with the message that higher absorbency is associated with a higher risk of TSS. * * *

2. Announce in the notice of proposed rulemaking that the agency intends to issue a final rule as expeditiously as possible and to make the rule effective upon publication so that manufacturers may immediately begin making plans for changing tampon labels in a manner that is consistent with the proposed rule.

3. Declare that any tampons sold after the effective date of the rule are misbranded under the Federal Food, Drug, and Cosmetic Act and that the agency will commit the necessary resources to enforce the final rule.

FDA will consider HRG's August 20, 1987, petition and any comments received on it when the agency considers the comments received on the proposed rule, and will include in any final rule or in any document withdrawing the proposed rule a final response to the petition.

G. FDA Reconsiders Its Position

The ASTM task force met frequently for more than 3 years. It appointed two subcommittees, one on test methods and the other on labeling, to prepare separate sections of the voluntary standard. The subcommittee on test methods agreed on the Syngyna test (see Sections F. and K. of this preamble) as the test method for measuring absorbent capacity. The subcommittee on labeling failed to reach agreement on an approach to tampon absorbency labeling. In an attempt to resolve the impasse at the subcommittee level, the full task force discussed a number of alternative approaches to tampon labeling, such as those set out in Section J. of this preamble. However, the full task force never reached a consensus either among the tampon manufacturers or between the manufacturers and the consumer members of the task force on a means for expressing tampon absorbency on labeling.

On April 16, 1984, a coalition of consumer and women's health organizations urged FDA to develop a comprehensive performance standard for tampons that would include standardized absorbency testing and labeling (Ref. 24).

On May 2, 1984, the task force unanimously passed a resolution tabling any further discussion of absorbency labeling. On April 18, 1985, the task force recommended to its parent ASTM committee that the task force become inactive because the task force could not resolve its differences regarding labeling. The task force has not met since that date.

Citing the failure of the task force to reach a consensus on a voluntary absorbency standard, HRG wrote to FDA on May 7, 1984 (Ref. 25). HRG requested that FDA reconsider its April 22, 1983, response to HRG (Ref. 21) and initiate a proceeding to establish a performance standard under section 514 of the act (21 U.S.C. 360d) for the device or, in the alternative, establish requirements with respect to a method for determining absorbency and with respect to a tampon labeling format for disclosing absorbency.

The failure of the ASTM effort led FDA to reconsider its position. In reconsidering, FDA once again reviewed the scientific data regarding tampon absorbency and TSS. FDA concluded that the data showed an association between tampon absorbency and TSS. Accordingly, on June 22, 1984 (Ref. 26), FDA advised HRG and the consumer and women's health organizations that had written to the agency on April 16, 1984, that the agency planned to promulgate a rule that would include a standardized absorbency test and absorbency labeling requirements for tampons (Ref. 24). FDA believed then, as it does now, that the scientific data support such a rule, which would allow women to choose the least absorbent tampon for their needs, thus reducing their relative risk of contracting TSS.

On August 20, 1985, FDA's Obstetrics-Gynecology Devices Panel (the Panel) discussed the safety of tampons in general, the association of tampons with TSS in particular, and the need to formulate a research agenda to investigate and address various safety concerns related to tampons. The Panel discussed each of these issues as requested in a citizen petition submitted by Woman Health International and the Empire State Consumer Association on September 11, 1984 (Ref. 30). The Panel supported (Ref. 31) FDA's plan to promulgate a tampon absorbency labeling regulation that would facilitate interbrand comparison, and recommended an absorbency rating system based on a single test method.

The Panel also recommended the FDA consider including "content" (ingredient) labeling in the tampon absorbency labeling regulation. This recommendation resulted from the Panel's discussion of ingredient labeling for scented tampons. During that discussion, a consumer group suggested that FDA regulate scented tampons as cosmetics so that, as cosmetics, scented menstrual tampons would be required to bear ingredient labeling.

However, if FDA regulated scented tampons as cosmetics, their labeling would not change. Under 21 CFR 701.3 (FDA's regulation governing the declaration of ingredients in cosmetics), a fragrance may be listed on the label of a cosmetic as "fragrance," and no further information is required on the label. The only manufacturer of scented tampons already lists "fragrance" as an ingredient. Accordingly, FDA has decided not to regulate tampons as cosmetics.

Because several consumers testified before the Panel in favor of ingredient labeling for other than scented tampons, FDA invites interested persons to submit comments with relevant data and information on the need for such labeling as well as on the kind of ingredient labeling that would be appropriate. The agency also invites such persons to submit comments setting out the basis for FDA to require ingredient labeling for other than scented tampons, under the act or any other law administrated by the agency.

H. Manufacturers' Voluntary Actions

On January 8, 1986, Mr. Edwin Shutt, Jr., President of Tambrands, Inc., wrote to FDA of Tambrands' intention to include absorbency labeling on all tampons marketed by the firm (Ref. 33). Mr. Shutt sent FDA an addendum to this letter on January 27, 1986 (Ref. 34), stating that Tambrands intended to use the Syngyna test method for absorbency proposed during the ASTM tampon task force deliberations. Tambrands also stated that it would use the following absorbency ranges to correspond to its existing absorbency terms: Junior—4 to 6 grams of fluid absorbed, Regular—6 to 9 grams, Super—9 to 12 grams, and Super Plus—12 to 16 grams.

On January 27, 1986, FDA wrote to the other tampon manufacturers informing them of Tambrands' intended actions and asking whether they planned to take any action regarding tampon absorbency testing and labeling (Ref. 35). On January 30, 1986, FDA sent a similar letter to a representative of several consumer groups asking for the groups' comments on Tambrands' proposed labeling scheme (Ref. 36). The responses the agency received from the tampon manufacturers and from the consumer groups are described below.

Responses from manufacturers: The other four manufacturers of tampons, International Playtex, Inc., Personal Products, Inc., Sentinel Consumer Products, and Kimberly-Clark Corp., responded that, like Tambrands, they would test their tampons for absorbency using the Syngyna test method (Refs. 38,

39, 40, and 41). However, the manufacturers did not agree on a labeling plan.

Two companies, Kimberly-Clark Corp. (Ref. 38) and Sentinel Consumer Products (Ref. 39), indicated that they would adopt a labeling plan using the absorbency ranges suggested by Tambrands and that they would retain their currently used absorbency terms. The combined sales of Tambrands and these two manufacturers represent about 70 percent of the tampon market.

Two other companies, International Playtex, Inc. (Ref. 40), and Personal Products, Inc. (Ref. 41), which represent approximately 30 percent of the tampon market, stated that they would label each style of their tampons with a single number representing absorbency in grams instead of using a range of absorbency and would also retain currently used terms of absorbency. These two firms stated that, to allow for variations in absorbency of tampons, the number placed on the label would be stated with an allowance of a plus or minus 1 gram variation. Thus, for example, a tampon that was determined by the Syngyna test to absorb 9 grams of the test solution would be characterized on the package label as absorbing 9±1 grams.

In sum, each tampon manufacturer voluntarily agreed to adopt the same absorbency testing method for tampons, but the manufacturers did not agree on a way to represent the results of this testing on tampon labeling, nor did they agree on a unified approach to the use of descriptive absorbency terms.

Responses from consumer groups: Representatives of two consumer groups responded to the January 30, 1986, letter (Refs. 42 and 43). The two groups supported Tambrands' approach, but stated that the agency needed to mandate a uniform approach in the face of the nonuniform approach offered by the industry. The two groups also stated that their views were widely shared among all the consumer groups listed in Section E. of the preamble who had been involved with the task force deliberations on a voluntary standard.

I. Basis for Proposed Rule

FDA is proposing a rule to ensure uniform absorbency testing of tampons and to standardize a method of expressing absorbency on tampon package labels. FDA is proposing this rule for several reasons. First, FDA believes that additional tampon absorbency information is necessary to enable menstruating women to make interbrand comparisons and choose the lowest absorbency needed to control menstrual flow and, thus, reduce their risk of contracting TSS. Second, a manufacturer's failure to provide absorbency information in the labeling constitutes omission of a material fact that misbrands the device under the act because current labeling does not provide adequate directions for tampon use and misleads consumers who want to use tampons with the minimum absorbency needed to control menstrual flow. Third, FDA has concluded that manufacturers will not voluntarily agree to provide absorbency information that will facilitate interbrand comparisons of tampons.

The act gives FDA broad authority to regulate medical devices for human use. The word "device" is defined in section 201(h) of the act. Under section 513 of the act (21 U.S.C. 360c), FDA has classified menstrual tampons as class II devices (performance standards) in 21 CFR 884.5460 and 884.5470.

Section 701(a) of the act (21 U.S.C. 371(a)) authorizes FDA to promulgate substantive binding regulations for the efficient enforcement of the act. *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); see also *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973); *National Ass'n of Pharmaceutical Manufacturers* v. *FDA*, 637 F.2d 877 (2d Cir. 1981); *National Confectioners Ass'n* v. *Califano*, 569 F.2d 690 (D.C. Cir. 1978); *National Nutritional Foods Ass'n* v. *Weinberger*, 512 F.2d 688 (2d Cir.), *cert. denied*, 423 U.S. 825 (1975).

Under the proposed rule, any tampon that is not labeled as requried and that is initially introduced or initially delivered for introduction into commerce after the effective date of a final rule would be misbranded under sections 201(n) and 502 (a) and (f)(1) of the act (21 U.S.C. 321(n) and 352 (a) and (f)(1)).

Section 502(a) of the act provides that a device is misbranded if "its labeling is false or misleading in any particular." Section 201(n) of the act provides that, in determining whether labeling of a regulated article (such as a device) is misleading:

> * * * there shall be taken into account * * * not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling * * * fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling * * * relates * * *.

Tampon labeling currently advises women to use tampons with the minimum absorbency needed. This advice is based on the association between increased absorbency and TSS. It is difficult, however, for women to heed this advice because there is no information on tampon labeling with which a woman can make interbrand comparisons with respect to absorbency. (Although manufacturers may use common terms to represent absorbency, these terms have different meanings across brands. For example, one manufacturer's tampon labeled as "regular" was found to absorb between 12 and 13 grams of fluid, while another manufacturer's "super" tampon absorbed only 9 grams. Moreover, between products labeled with the same term, e.g., "super," FDA has found a variance in absorbency of up to 7 grams (Ref. 27).) This omission of uniform absorbency information from the labeling constitutes an omission of a material fact and renders tampons misbranded within the meaning of section 502(a) of the act.

The courts have upheld FDA's authority to prevent false and misleading labeling by promulgating regulations requiring label warnings and other affirmative disclosures, see, e.g., *Cosmetic, Toiletry and Fragrance Association* v. *Schmidt*, 409 F. Supp. 57 (D.D.C. 1976), *aff'd without opinion*, Civil No. 75–1715 (D.C. Cir. August 19, 1977), even in the absence of a proven cause-and-effect relationship between product usage and harm. *Council for Responsible Nutrition* v. *Goyan*, Civil No. 80–1124 (D.D.C. August 1, 1980).

Section 502(f)(1) of the act provides that a device is also misbranded unless its labeling bears adequate directions for use. Adequate directions for use means adequate directions under which a layperson can use a device safely and for the purpose for which it is intended (see 21 CFR 801.5 and 801.6). A woman cannot use tampons safely if she cannot determine which tampons have the minimum absorbency that she needs to control menstrual flow. Because current tampon labeling does not contain any information with which a woman can determine the relative absorbency of different brands of tampons, tampons do not bear adequate directions for use, and therefore are misbranded under section 502(f)(1) of the act.

FDA may impose testing requirements in a labeling regulation promulgated under its general rulemaking authority. See, e.g., *American Frozen Food Inst.* v. *Mathews*, 413 F. Supp. 548 (D.D.C. 1976), *aff'd per curiam sub nom. American Frozen Food Inst.* v. *Califano*, 555 F.2d 1059 (D.C. Cir. 1977); see also *National Nutritional Foods Ass'n* v. *Weinberger*, *supra*. Thus, FDA may require that all tampon manufacturers use the same test

method to determine absorbency, to ensure that there is uniformity in measuring tampon absorbency. A similar requirement is imposed in 21 CFR 801.420(c)(4) on hearing aid manufacturers and distributors who must determine and state technical data values for hearing aid labeling in accordance with specified test procedures. The hearing aid regulation has been upheld. *American Speech and Hearing Ass'n* v. *Califano*, Med. Devices Rept. (CCH) No. 77–1327, §§ 15,004, 15,007 (D.D.C. August 23, 1977), *aff'd*, No. 77–1327 (D.C. Cir. Dec. 19, 1977). Food regulations promulgated under section 701(a) of the act also impose many such specific testing requirements. See, e.g., 21 CFR 113.40 (tests for low-acid canned foods); 21 CFR 155.190(b)(2)(i) (test for determining drained weight of canned tomatoes); 21 CFR 161.190 (method for determining color designation of tuna).

The proposed rule does not require that tampons perform at a specified level of absorbency, only that each manufacturer measure the absorbency of its tampons and state the results on package labeling.

J. Other Options for Expressing Absorbency on Package Labels Considered by FDA

FDA is proposing to require absorbency to be expressed on tampon labels using letter designations of the ranges of absorbency. Before deciding on this approach, FDA considered alternative approaches, as described below. These alternatives, and the approach FDA has selected, are based on the agency's understanding of the currently available manufacturing technology and data on incremental TSS risk associated with increased absorbency. Ideally, a very small variation in absorbency would exist for all production of a single style of tampon, such that the range of absorbencies contained in a given box could be accurately represented, for example, by a single number. Combining such information on absorbency with a clear indication that each increment in absorbency was associated with an increase in TSS risk would allow FDA to consider more narrow absorbency range categories. Although FDA is inviting comments on the relative advantages and disadvantages of the alternative approaches described below, the agency also solicits information and comments on the technical feasibility of offering more absorbency ranges, without significant overlap in absorbencies of products in adjacent ranges.

1. Absorbency Values

FDA considered proposing to require that absorbency be represented on tampon labeling by a single number, rather than by a range. This alternative is similar to that described in the August 20, 1987, petition from HRG discussed in section F. of this preamble. With this alternative, if a tampon manufacturer determined that a particular tampon style absorbed, on average, 7 grams of fluid, the manufacturer would represent the absorbency of such tampons as "7" on the label. However, because the "7" would represent an average absorbency, any one tampon in a package might actually absorb fewer than 6 grams of fluid or more than 8 grams of fluid. Variations in raw materials, production, and even testing contribute to this uncertainty. For example, the absorbency of a raw material such as cotton may be influenced by its natural moisture content, which in turn may be affected by the geographical area in which it is grown and by the conditions under which it is harvested, transported, and stored. The humidity level at the time of tampon production may also cause batch-to-batch or run-to-run variations in absorbency. In addition, minor differences in testing procedures among laboratories and within a given laboratory could cause differences in results of absorbency testing. Thus, although FDA believes that a single number representing absorbency would be easy for consumers to understand, the agency does not believe that, at this time, a single number is sufficiently accurate. Moreover, FDA does not believe that, using currently available technology, it is possible to make a tampon the absorbency of which is accurately represented by a single number. Should technology, quality control, and testing improve to the extent that variation is significantly reduced, however, this alternative would be more viable.

FDA also considered proposing that absorbency be expressed with a single number followed by "± 'X'" grams in order to more accurately express absorbency, given the variations between individual tampons in a single box, while retaining some of the simplicity of a single number. FDA believes, however, that this approach might be confusing to some consumers. For example, a box of tampons labeled "absorbency 7± 1.5 grams" would contain some tampons that actually absorb more than tampons from a box labeled "absorbency 9± 1.5 grams." FDA is concerned that many consumers would focus on the "7" and the "9" and not recognize this overlap in absorbency. (FDA has other concerns about overlappping absorbencies which will be discussed below.)

Therefore, to clearly express the variation in absorbency of tampons of a particular style, FDA has proposed that manufacturers represent absorbency using ranges. Ranges allow an accurate expression of the variation in absorbency of individual tampons, provide consumers with meaningful information, and are technologically feasible.

FDA considered a proposal allowing manufacturers the flexibility to market an unlimited number of absorbency ranges. This approach would be technologically feasible and would offer the theoretical advantage of providing for the development of a greater variety of products, thus increasing consumer choice. At the same time, however, this approach could result in product lines with overlapping absorbencies. For example, one product could be labeled "absorbency 6–9 grams" and another product could be labeled "absorbency 7–10 grams."

While consumers would be expected to notice that the ranges overlap, FDA is concerned that, under this approach, consumers could have the misleading impression that tampons in a "7–10" package are all more absorbent than tampons in a "6–9" package. In fact, however, there would be tampons in the "6–9" package that would be more absorbent, and thus pose a higher risk of TSS, than many tampons in the "7–10" package. To show this, a representation of the distribution of product absorbencies for tampons in a 6–9 gram absorbency range is set out in figure A.

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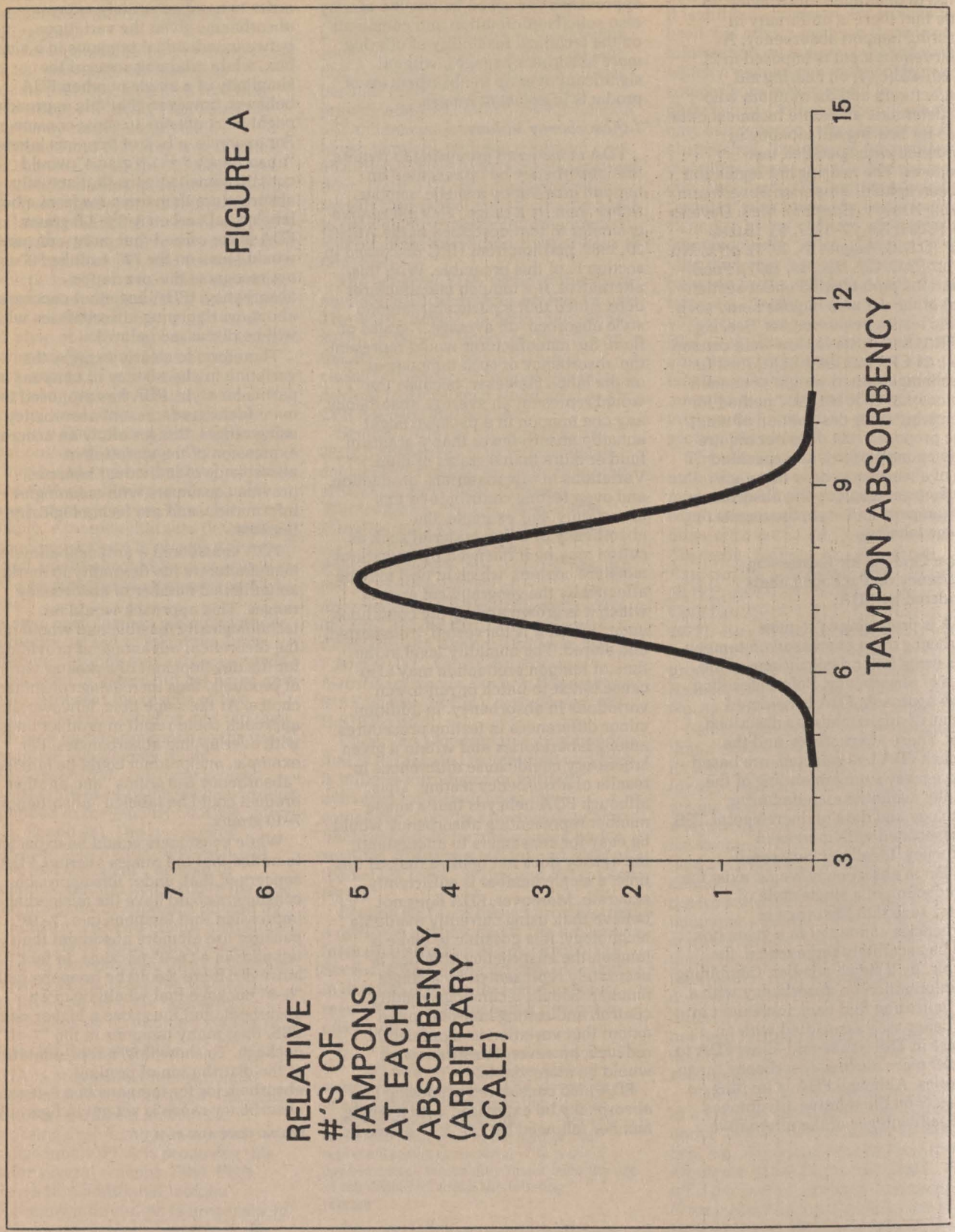
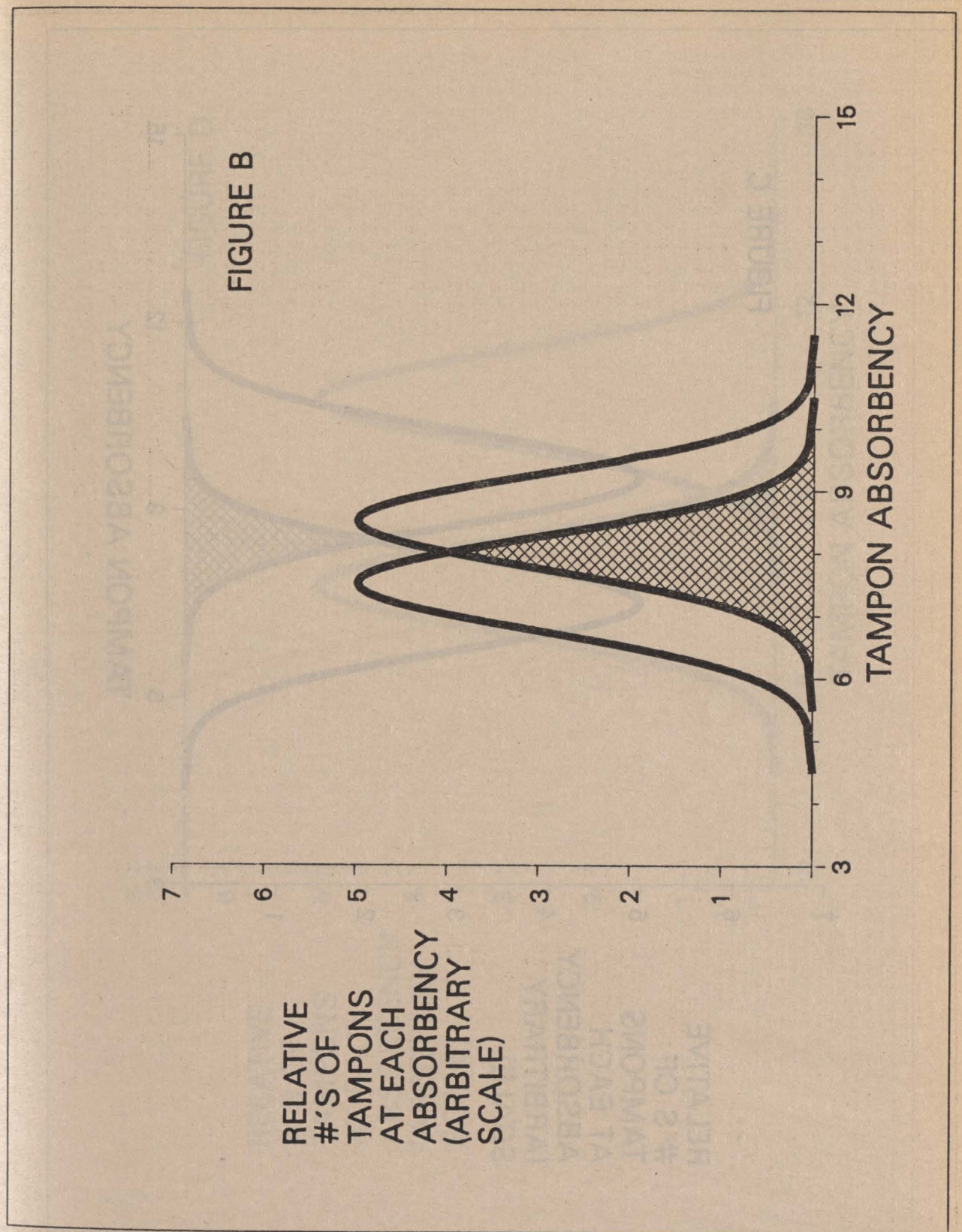
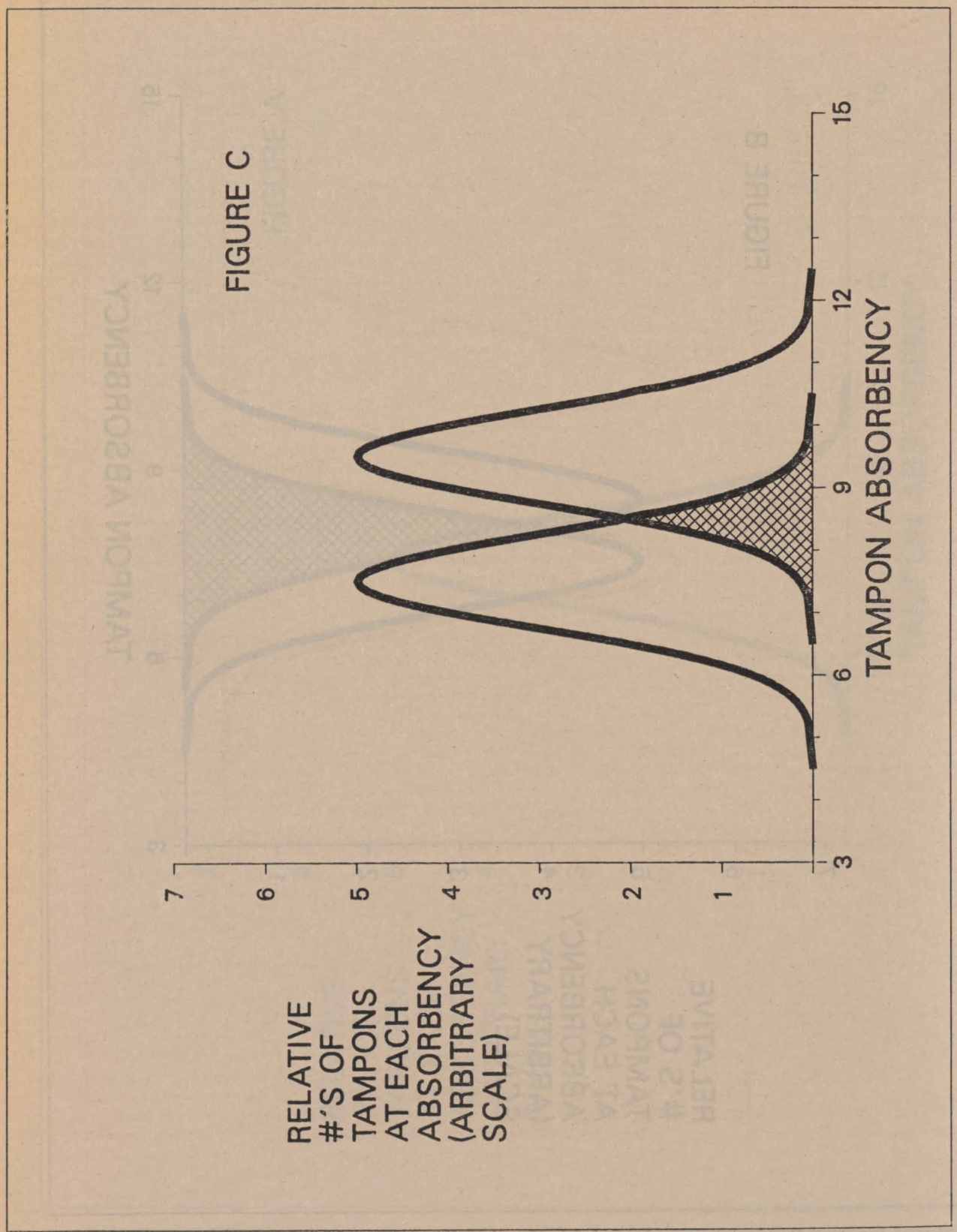


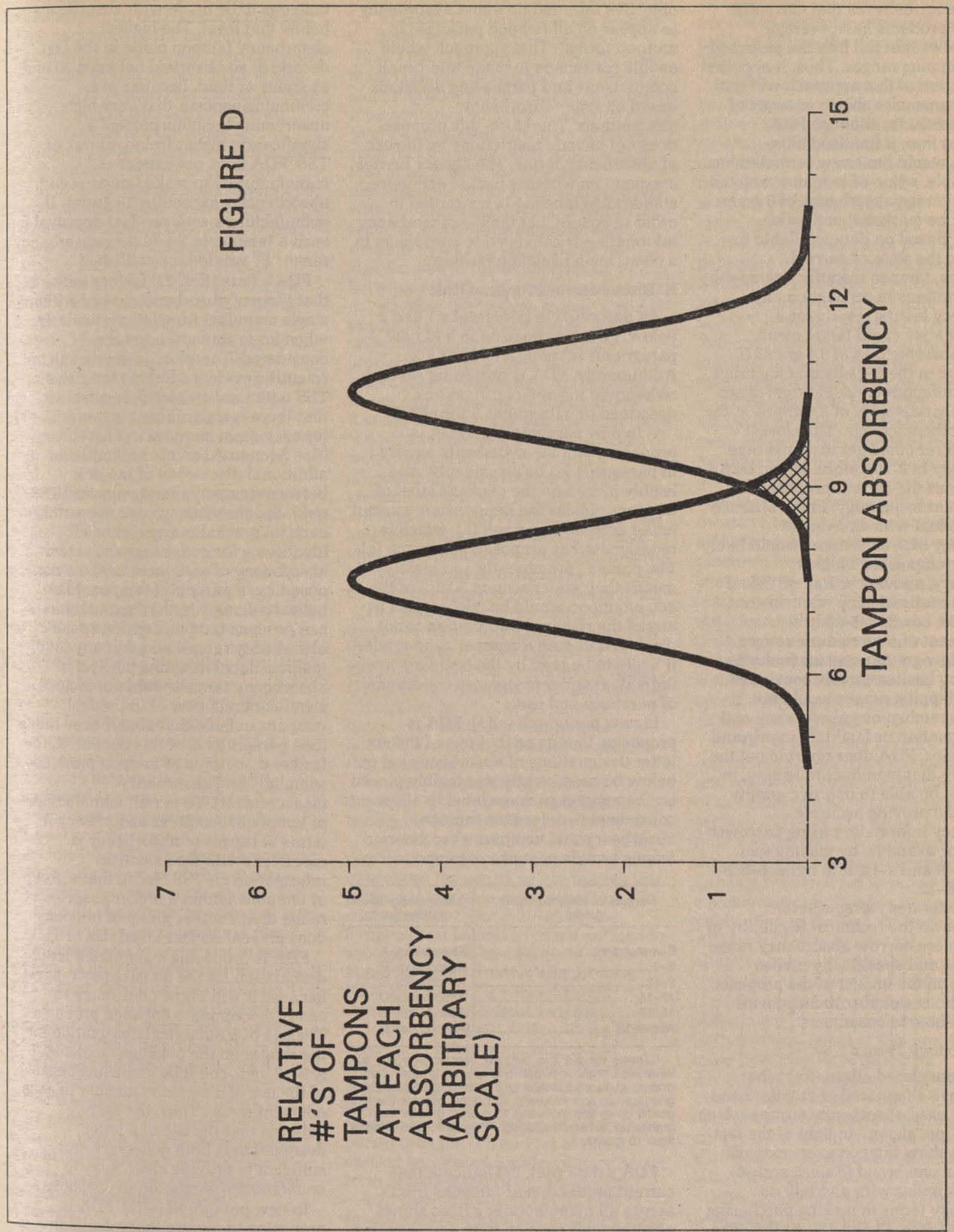
For comparison purposes, a similar representation for tampons in a 7–10 gram absorbency range is added in figure B.



The shaded area in Figure B shows the overlap between the ranges and demonstrates that the absorbency and risk of TSS associated with tampon from a package with the lower range could be larger than that of a tampon from the higher range package. The region of overlap is reduced, but still pronounced in figure C, which compares a 6–9 gram absorbency range with an 8–11 gram absorbency range.



Only when a 6–9 gram absorbency range is compared with a 9–12 gram absorbency range is the overlap significantly reduced, as seen in figure D.



Thus, only in this latter case with virtually nonoverlapping ranges could consumers be assured that products in a lower range had lower absorbency and presented a lower risk of TSS than those in a higher range. Accordingly, FDA is proposing to have tampon absorbencies fall into nonoverlapping ranges.

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The agency believes that currently marketed products have average absorbencies that fall into the proposed nonoverlapping ranges. Thus, it appears that adoption of this approach will not diminish consumer choice in terms of existing products, although FDA recognizes that, if finalized, this approach would limit new formulations. For example, a line of tampons targeted with an average absorbency of 9 grams could not be marketed under this proposal. Based on data available to FDA as to the state of current technology, tampon manufacturers with small variations in production and absorbency testing results for a particular style could target mean product absorbencies of 8.4 grams in order to be in the 6–9 absorbency range. Such manufacturers could target mean product absorbencies of 9.6 grams in the 9–12 absorbency range. The closest a manufacturer could get to an average absorbency of 9, therefore, would be 8.4 or 9.6, under the current proposal and with current technology. In the absence of the product with an average absorbency of 9, consumers would likely choose a tampon with higher absorbency, and higher risk of TSS, if any greater absorbency were desired. While FDA concludes that the development of intermediate ranges would allow greater consumer choice, the agency has tentatively concluded that overlapping ranges would not provide unambiguous absorbency and risk information or facilitate interbrand comparisons. FDA does not rule out the possibility that manufacturers may, in the future, be able to improve quality control and provide accurate absorbency information using narrower ranges, for example, by making two ranges, 6–9 and 9–12, into three, 6–8, 8–10, and 10–12.

FDA reiterates its request for comments on the technical feasibility of offering more narrow absorbency range categories and specifically invites comment on the impact of the proposed rule on choices of absorbency levels now available to consumers.

2. Absorbency Terms

FDA considered alternatives that would have eliminated or standardized currently used absorbency terms such as "regular" or "super," in light of the fact that data show tampon users may use more than one brand (Refs. 5 and 46) and are familiar with and rely on absorbency terms in making purchasing decisions (Refs. 33 and 43). At this time, women must rely in part on absorbency terms for interbrand comparisons. The labeling system envisioned in this proposal, however, would require objective information about absorbency to appear on all tampon packages in a uniform format. This approach would enable consumers to make interbrand comparisons and purchasing decisions based on letter absorbency designations. Therefore, this proposal does not include restrictions on the use of absorbency terms. The agency invites comment on whether further action to standardize labeling is warranted in order to ensure that tampon absorbency information is conveyed to consumers in a clear, nonmisleading fashion.

K. Discussion of Proposed Rule

As described in paragraphs 1 and 2 below, FDA is proposing to add new paragraphs (e) and (f) to § 801.430. Additionally, FDA is proposing several redesignations and clarifications described in paragraphs 3 through 6.

1. In new paragraph (e), FDA is proposing that the statements required in paragraph (e) be prominently and legibly placed on the package label of tampons, unless the tampons are exempt under current paragraph (e), which is redesignated as proposed paragraph (g). The phrase "prominently and legibly" means that, under section 502(c) of the act, a tampon would be misbranded if any of the required information is not displayed in such a manner as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

In new paragraph (e)(1), FDA is proposing to require that one of the six letter designations of absorbency set out below be prominently and legibly placed on the tampon package label to allow consumers to determine tampon absorbency and compare absorbency among brands or styles of tampons.

Ranges of absorbency in grams [1]	Letter designation of absorbency
6 and under	Absorbency A.
6–9	Absorbency B.
9–12	Absorbency C.
12–15	Absorbency D.
15–18	Absorbency E.
Above 18	Absorbency F.

[1] These ranges are defined, respectively, as follows: less than or equal to 6 grams; greater than 6 grams up to and including 9 grams; greater than 9 grams up to and including 12 grams; greater than 12 grams up to and including 15 grams; greater than 15 grams up to and including 18 grams; and greater than 18 grams.

FDA's data (Ref. 27) indicate that current production of tampons from across all manufacturer's lines shows absorbencies ranging from 4 to 18 grams. Because of the reduced effectiveness of tampons with absorbency of less than 4 grams in preventing leakage of menstrual fluid, FDA does not expect tampons to be made with absorbency below that level. The highest absorbency tampon made in the last decade or so absorbed between 20 and 21 grams of fluid. Because of a continuing concern that very high absorbency tampons present a significantly higher (relative) risk of TSS, FDA does not expect manufacturers to make tampons with absorbencies exceeding 18 grams. If manufacturers seek product approval for such a tampon in the future, absorbancy range "F" would be established.

FDA's data (Ref. 27) further indicate that tampon absorbencies vary within a single manufacturing lot, particularly when lot-to-lot variations are considered. Therefore, even though the scientific evidence linking the risk of TSS with tampon absorbency shows that there is a significant increase in risk for each gram increase in absorbency (See Section A. of this preamble for additional discussion of the link between tampon absorbency and TSS risk), the absorbency variance within each lot precludes any means of identifying for consumers the actual absorbency of and, therefore, the risk posed by, a particular tampon. FDA believes, however, that manufacturers can produce tampons within specific absorbency ranges and that any lot of tampons labeled with a particular absorbency range should not include significant numbers of individual tampons outside that absorbency range (See paragraph 2. of this Section K. for further discussion of tampon production, sampling, and absorbency measurement). To permit manufacturers of tampons to express absorbency in terms of ranges of absorbency is consistent with the scientific information on TSS risk in that a group of tampons within a higher absorbency range than another group of tampons does present an increased risk of TSS.

FDA is proposing a simplified letter designation for the abosrbency ranges because it will allow consumers to easily discriminate between products. The use of a numerical designation for the ranges on the package label, e.g., 6–9, 9–12, etc., could be confusing because of the use of a common number in each adjacent range. Thus, the agency believes that the use of a letter designation is both necessary and sufficent to provide clear, easy to understand information to consumers.

In new paragraph (e)(2), FDA is proposing to require that manufacturers include on the package label an explanation of the range of absorbency shown on that label. For example, a tampon package labeled "Absorbency

B" would be required to bear an explanation that each tampon enclosed in the package has the capacity to absorb more than 6 grams and up to and including 9 grams of fluid. FDA is also proposing to require that manufacturers describe on the package label how consumers can use the range of absorbency, e.g., consumers should use the absorbency ranges to compare different tampon brands and styles and choose the minimum absorbency needed to control menstrual flow and, thereby, reduce the risk of contracting TSS.

In new paragraph (e)(3), FDA is proposing that terms currently used in labeling to represent absorbency (e.g., regular, super, and super plus) of tampons may continue to be used in the labeling provided that, if a term of absorbency is used, it is required to be placed on the package label in close proximity to its corresponding letter designation of the range of absorbency each time the term of absorbency is used.

The agency is specifically requesting public comment as to whether these proposed labeling requirements would influence consumer choices in selecting a tampon with a lower absorbency level.

2. In new paragraph (f), FDA is proposing to require that manufacturers use a test based on the tampon absorbency testing method (the Syngyna test) that was agreed upon by the ASTM task force's subcommittee on test methods (Refs. 15, 17, and 27). (See Section G. of this preamble.)

To evaluate the feasibility of the Syngyna test, FDA sampled and tested tampons to determine if their fluid absorbency as measured by the Syngyna test was homogeneous from lot-to-lot and from run-to-run within given lots (Ref. 27). The data show that there is a distribution of absorbencies represented by tampons in a single lot. That distribution tends to widen as lot-to-lot variations are considered. Such variations would be expected to occur because of differences in raw material (e.g., cotton, rayon) or in production conditions (humidity). The data show that statistical tolerance limits can be placed such that the probability is 95 percent that the fluid absorbency values for a given brand and tampon style lie within the stated tolerance limits, if mean absorbency is rounded to the nearest 0.1 gram. Based on these data, FDA believes that it is feasible for manufacturers to use the Syngyna test method to determine tampon absorbency.

Accordingly, in new paragraph (f), FDA is proposing to require that manufacturers measure the absorbency of individual tampons and calculate the mean absorbency of the production run, lot, or batch by rounding to the nearest 0.1 gram. Further, in new paragraph (f)(1), FDA is proposing to require that manufacturers design and implement a sampling plan that includes collection of representative samples of adequate size to yield consistent tolerance intervals such that the probability is 95 percent that at least 95 percent of the absorbencies of the individual tampons within a brand and style fall within the range of absorbency stated on the package label, i.e., there will be no significant overlap in absorbency between ranges. Where a manufacturer experiences differences in raw material or production conditions such that a wide distribution of absorbencies is produced within a style, the manufacturer would have to increase its sampling and testing to demonstrate that the outlying high and low absorbing tampons in the lot or run are actually small in number. In the case of a demonstrably narrow distribution of abosrbencies within a style, the manufacturer could reduce its sampling and testing and still demonstrate that only a small number of tampons in the lot or run could be outside the absorbency range on the package label.

The agency invites comments on the degree to which this approach assures that there are a small number of tampons outside the absorbency range stated on the package label and whether a tolerance level of 90 percent as opposed to the 95 percent proposed in this rule would be sufficient to provide that assurance.

In new paragraph (f)(2), FDA describes the proposed absorbency testing method, the Syngyna test.

In new paragraph (f)(3), FDA would require that a manufacturer that wants to propose the use of an alternative test method that yields results that are equivalent to those yielded by the Syngyna test submit a citizen petition in accordance with 21 CFR 10.30. If FDA approves an alternative test method, FDA will publish a notice of such approval in the **Federal Register.**

3. In current § 801.430(b), in the last sentence, FDA is proposing to add reference to new paragraphs (e) and (f). FDA is proposing that the last sentence read in pertinent part "* * * menstrual tampons shall be labeled as set forth in paragraphs (c), (d), and (e) of this section and tested for absorbency as set forth in paragraph (f) of this section."

4. In current § 801.430(d)(3), FDA is proposing to conform the language used to the information in proposed new § 801.430(e)(2). Thus, FDA is proposing that § 801.430(d)(3) be revised to read as follows: "(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS."

5. FDA is proposing to redesignate current paragraph (e) as paragraph (g), with a minor clarification. FDA is proposing that new paragraph (g) read as follows: "Any menstrual tampon intended to be dispensed by a vending machine is exempt from the requirements of this section." FDA stated in the preamble to the final rule published in the **Federal Register** of June 22, 1982 (47 FR 26988) requiring manufacturers to include information about TSS in the labeling of tampons, that any tampon dispensed by a vending machine is exempt from the requirements. FDA had concluded that it is not necessary to have TSS information either on vending machine tampons or on the outside of the vending machine itself because women only infrequently purchase tampons from vending machines and will be made aware of the association between TSS and tampons from the tampons they purchase from other retail sources. FDA continues to exempt vending machine tampons from the TSS information requirements of § 801.430 and is proposing to exempt them from the absorbency labeling requirements as well. The agency is, however, specifically requesting public comments on these exemptions.

6. FDA is proposing to redesignate current paragraph (f) as paragraph (h) and revise it to state the effective date of any final rule based upon this proposal. FDA is proposing that any final rule become effective as to any tampon that is initially introduced or initially delivered for introduction into commerce 6 months after its date of publication in the **Federal Register.** Although FDA believes that a 6-month effective date is reasonable for relabeling, the agency understands that, if reformulation or redesign is undertaken (on a manufacturer's own initiative as a result of this proposal), more time may be required for developing and implementing new production methods. Therefore, FDA invites comments and supporting data on any need for an effective date greater than 6 months (and if any need, how long), after publication of a final rule.

FDA also is proposing in redesignated paragraph (h) that any menstrual tampon not labeled as required in § 801.430 (c), (d), and (e) is misbranded under sections 201(n) and 502 (a) and (f) of the act.

L. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. "Epidemiologic Notes and Reports: Follow-up on Toxic-Shock Syndrome—United States," *Morbidity and Mortality Weekly Report*, Centers for Disease Control, June 27, 1980, Vol. 29, No. 25.

2. "Epidemiologic Notes and Reports: Follow-up on Toxic-Shock Syndrome," *Morbidity and Mortality Weekly Report*, Centers for Disease Control, September 19, 1980, Vol. 29, No. 37.

3. "Toxic-Shock Syndrome—Utah," *Morbidity and Mortality Weekly Report*, Centers for Disease Control, October 17, 1980, Vol. 29, No. 40.

4. Davis, J.P., et al., "Toxic-Shock Syndrome," *New England Journal of Medicine*, 303:1429–1435, December 18, 1980.

5. Osterholm, M.T., et al., "Tri-State Toxic-Shock Syndrome Study. I. Epidemiologic Findings," *Journal of Infectious Diseases*, 145:431–440, April 1982.

6. Institute of Medicine, National Academy of Sciences, "Toxic-Shock Syndrome: Assessment of Current Information and Future Research Needs," National Academy Press, Washington, DC, 1982.

7. Osterholm, M.T., et al, "Toxic Shock Syndrome Study: Methodologic Analysis," *Annals of Internal Medicine*, 96:903–905, June 1982.

8. Osterholm, M.T., et al., "Tri-State Toxic-Shock Syndrome Study: Evaluation of Case Definition and Prevention of Recurrence," *Annals of Internal Medicine*, 96:903–905, June 1982.

9. Harvey, M., et al., "Toxic Shock and Tampons, Evaluation of the Epidemiologic Evidence," *Journal of the American Medical Association*, 248:840–846, August 20, 1982.

10. Harvey, M., et al., "Diagnostic Bias and Toxic Shock Syndrome," *American Journal of Medicine*, 76:351–360, March 1984.

11. Hulka, B. S., "Tampons and Toxic Shock Syndrome (editorial)," *Journal of the American Medical Association*, 248:872–874, August 20, 1982.

12. Marlowe, D.E., "Measurement of Tampon Absorbency—Evaluation of Tampon Brands," Center for Medical Device Analysis Report No. 81–017, June 29, 1981.

13. Letter from John C. Villforth to "Tampon Manufacturers," June 1983.

14. Letter from F. Alan Andersen to Patrick G. Laing, Chairman, Subcommittee F4, Medical and Surgical Materials and Devices, American Society for Testing and Materials, July 13, 1981.

15. Rapp, G.W., "A Comparison of the Absorptive Efficiency of Commercial Catamenial Tampons," unpublished, June 1958.

16. Marlowe, D.E., R.M., Weigle, and R.W. Stauffenberg, "Measurement of Tampon Absorbency: Test Method Evaluation," Center for Medical Device Analysis Report No. 81–013, May 1981.

17. Technical Task Group Tampon Task Force—ASTM F–4.02, "Tampon Absorbency Interlaboratory Evaluation Production Evaluation," unpublished, November 1983.

18. Petition from Public Citizen Health Research Group to the Food and Drug Administration, July 29, 1982.

19. Letter from Mark Novitch to Sidney M. Wolfe and Allen Greenberg, September 22, 1982.

20. Letter from Allen Greenberg, Sidney M. Wolfe, and William B. Schultz to Mark Novitch, November 2, 1982.

21. Letter from Mark Novitch to Sidney M. Wolfe and Allen Greenberg, April 22, 1983.

22. Letter from David A. Swankin to John C. Villforth, August 19, 1983.

23. Letter from John C. Villforth to David A. Swankin, January 9, 1984.

24. Letter from a coalition of consumer and women's health groups to Mark Novitch, April 16, 1984.

25. Letter from Allen Greenberg and Sidney M. Wolfe to Mark Novitch, May 7, 1984.

26. Letter from Mark Novitch to Rebecca Cohen, June 22, 1984.

27. "Determination of Fluid Capacity of Some Commercial Tampons," October 1984; report entitled "Tampon Fluid Capacity Measurements," Winchester Engineering and Analytical Center, January 20, 1985; memo from Richard Chiacchierini to Director, Office of Science and Technology, on the subject of tampon absorbency analysis, January 22, 1985; memo from Richard Chiacchierini to Alan Andersen on the subject of tampon absorbency analysis, February 8, 1985.

28. Mills, J.T., et al., "Control of Production of Toxic Shock Syndrome Toxin-1 (TSST–1) by Magnesium Ion," *Journal of Infectious Diseases*, 151:1158–1161, June 1985.

29. Interagency agreement between the Centers for Disease Control and the Food and Drug Administration; Approved and accepted by CDC on May 30, 1985, and by FDA on June 18, 1985.

30. Petition from Woman Health International and Empire State Consumer Association to the Food and Drug Administration, September 11, 1984.

31. Transcript of Obstetrics/Gynecology Devices Panel, Thirty-Second meeting, Vol. II, August 20, 1985.

32. Memorandum of Telephone Communication between Keith Merril and Lillian Yin, March 29, 1985.

33. Letter from Edwin Shutt, Jr., to John C. Villforth, January 8, 1986.

34. Letter from Edwin Shutt, Jr., to John C. Villforth, January 27, 1986.

35. Letters from John C. Villforth to International Playtex, Inc.; Personal Products, Inc.; Sentinel Consumer Products; and Kimberly-Clark Corp., January 27, 1986.

36. Letter from John C. Villforth to David A. Swankin, January 30, 1986.

37. Unpublished data, Centers for Disease Control, 1987.

38. Letter from Thomas A. Newby, Jr., to John C. Villforth, February 24, 1986.

39. Letter from Robert R. Arrighi to John C. Villforth, March 25, 1986.

40. Letter from Hercules P. Soto to John C. Villforth, February 26, 1986.

41. Letter from M.R. Hayes to John C. Villforth, February 12, 1986.

42. Letter from Esther R. Rome and Jill Wolhandler to John C. Villforth, February 13, 1986.

43. Letter from David A. Swankin to John C. Villforth, February 25, 1986.

44. Roper Reports 86–9, The Roper Organization, Inc., November 1986.

45. Medical Device Reporting Summary Data, December 1984 through May 1987.

46. Berkley, S.F., et al., "The Relationship of Tampon Characteristics to Menstrual Toxic Shock Syndrome," *Journal of the American Medical Association*, 258: 917–920, August 21, 1987.

47. Memorandum from Chief, Meningitis and Special Pathogens Branch, Division of Bacterial Diseases, Center for Infectious Diseases to Director, Office of Program Planning and Evaluation, Centers for Disease Control, October 19, 1987.

M. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

N. Economic Impact

FDA has examined the economic consequences of the proposed rule in accordance with the criteria in section 1(b) of Executive Order 12291 and found that the rule, if promulgated, will not be a major rule under Executive Order. The agency also has considered the effect that the proposed rule would have on small entities including small businesses. The agency believes that none of the affected manufacturers meets the definition of a small entity under the Regulatory Flexibility Act (Pub. L. 96–354). Therefore, FDA certifies under the Regulatory Flexibility Act that the proposed rule would not have significant economic impact on a substantial number of small entities.

There are five major manufacturers of tampons in the United States. These manufacturers' tampon products comprise 99 percent of the market. FDA estimates that this regulation will impose direct costs of $66,000 on each tampon manufacturer for redesignating and printing labels, redesignating package inserts, and absorbency testing. If manufacturers choose to reformulate products to have a tampon style in a greater number of ranges, they may incur additional direct costs of about $6 million each. Additionally, there are 11 private label manufacturers or distributors of store brand tampons. FDA estimates that this regulation will impose costs of $2,240 on each of these private label manufacturers or distributors for redesigning and printing labels and package inserts. A further description of these costs and the methods for estimating them can be

found in the threshold assessment on file with the Dockets Management Branch (address above).

Section 801.430(e) and (f) of this proposed rule contains collection of information requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980, FDA has submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of these collection of information requirements. Other organizations and individuals desiring to submit comments on the collection of information requirements should direct them to FDA's Dockets Management Branch (address above) and to the Office of Information and Regulatory Affairs, OMB, Rm. 3208, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

O. Request for Comments

Interested persons may, on or before December 22, 1988, Submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, it is proposed that Part 801 be amended as follows:

PART 801—LABELING

1. The authority citations under the sections in 21 CFR Part 801 are removed and the authority citation for 21 CFR Part 801 is revised to read as follows:

Authority: Sec. 701, 52 Stat. 1055–1056 as amended (21 U.S.C. 371); 21 CFR 5.10, § 801.420 also is issued under secs. 201 (h), (k), (m), and (n), 502, 519, 520(e), 704, 52 Stat. 1041 as amended, 1050–1051 as amended, 67 Stat. 477 as amended, 90 Stat. 564–565, 567, 575 (21 U.S.C. 321 (h), (k), (m), and (n), 352, 360i, 360j(e), 374); § 801.430 is issued under secs. 201(n), 502, 701(a), 52 Stat. 1041 as amended, 1050–1051 as amended, 1055 (21 U.S.C. 321(n), 352, 371(a)); 21 CFR 5.11.

2. Section 801.430 is amended by revising paragraphs (b) and (d)(3), by redesignating paragraphs (e) and (f) as paragraphs (g) and (h), respectively, and revising them, and by adding new paragraphs (e) and (f) to read as follows:

§ 801.430 User labeling for menstrual tampons.

* * * * *

(b) Data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to minimize the serious effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c), (d), and (e) of this section and tested for absorbency listed in this paragraph representing the absorbency as set forth in paragraph (f) of this section.

* * * * *

(d) * * *

(3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS.

* * * * *

(e) The statements required by this paragraph shall be prominently and legibly placed on the package label of menstrual tampons in conformance with section 502(c) of the act (unless the menstrual tampons are exempt under paragraph (g) of this section).

(1) Menstrual tampon package labels shall bear one of the six letter designations of absorbency of the production run, lot, or batch as measured by the test described in paragraph (f) of this section.

Ranges of absorbency in grams [1]	Letter designation of absorbency
6 and under	Absorbency A.
6–9	Absorbency B.
9–12	Absorbency C.
12–15	Absorbency D.
15–18	Absorbency E.
above 18	Absorbency F.

[1] These ranges are defined, respectively, as follows: less than or equal to 6 grams; greater than 6 grams up to and including 9 grams; greater than 9 grams up to and including 12 grams; greater than 12 grams up to and including 15 grams; greater than 15 grams up to and including 18 grams; and greater than 18 grams.

(2) The package label shall include an explanation of the range of absorbency and a description of how consumers can use the range of absorbency to make comparisons of absorbency of tampons to allow selection of the tampons with the minimum absorbency needed to control menstrual flow in order to reduce the risk of contracting TSS.

(3) Use of terms of absorbency is optional. If a term of absorbency (e.g., Regular, Super, or Super Plus) is used, its corresponding letter designation of the range of absorbency shall be placed on the package label in close proximity each time the term of absorbency is used.

(f) A manufacturer shall measure the absorbency of individual tampons using the test method specified in paragraph (f)(2) of this section and calculate the mean absorbency of a production run, lot, or batch by rounding to the nearest 0.1 gram.

(1) A manufacturer shall design and implement a sampling plan that includes collection of representative samples of adequate size to yield consistent tolerance intervals such that the probability is 95 percent that at least 95 percent of the absorbencies of individual tampons within a brand and type are within the range of absorbency stated on the package label.

(2) In the absorbency test, an unlubricated condom is attached to the large end of a glass chamber with a rubber band (see Figure 1) and pushed through the small end of the chamber using a smooth, finished rod. The condom is pulled through until all slack is removed. The tip of the condom is cut off and the remaining end of the condom is stretched over the end of the tube and secured with a rubber band. A preweighed (to the nearest 0.01 gram) tampon is placed within the condom membrane so that the center of gravity of the tampon is at the center of the chamber. An infusion needle (14 gauge) is inserted through the septum created by the condom tip until it contacts the end of the tampon. The outer chamber is filled with water pumped from a temperature-controlled waterbath to maintain the average temperature at 27±1 °C. The water returns to the waterbath as shown in Figure 2. Syngyna fluid (10 grams sodium chloride, 0.5 gram Certified Reagent Acid Fuchsin, 1,000 milliliters distilled water) is then pumped through the infusion needle at a rate of 50 milliliters per hour. The test is terminated when the tampon is saturated and the first drop of fluid exits the apparatus. The water is then drained and the tampon is removed and immediately weighed to the nearest 0.01 gram. The absorbency of the tampon is determined by subtracting its dry weight from this value.

(3) The Food and Drug Administration may permit the use of an absorbency test method different from the test method specified in this section if the following conditions are met:

(i) The manufacturer presents evidence, in the form of a citizen petition submitted in accordance with the requirements of § 10.30 of this chapter, demonstrating that the alternative test method will yield results that are equivalent to the results yielded by the test method specified in this section; and

(ii) FDA approves the method and has published notice of its approval of the alternative test method in the **Federal Register.**

BILLING CODE 4160-01-M

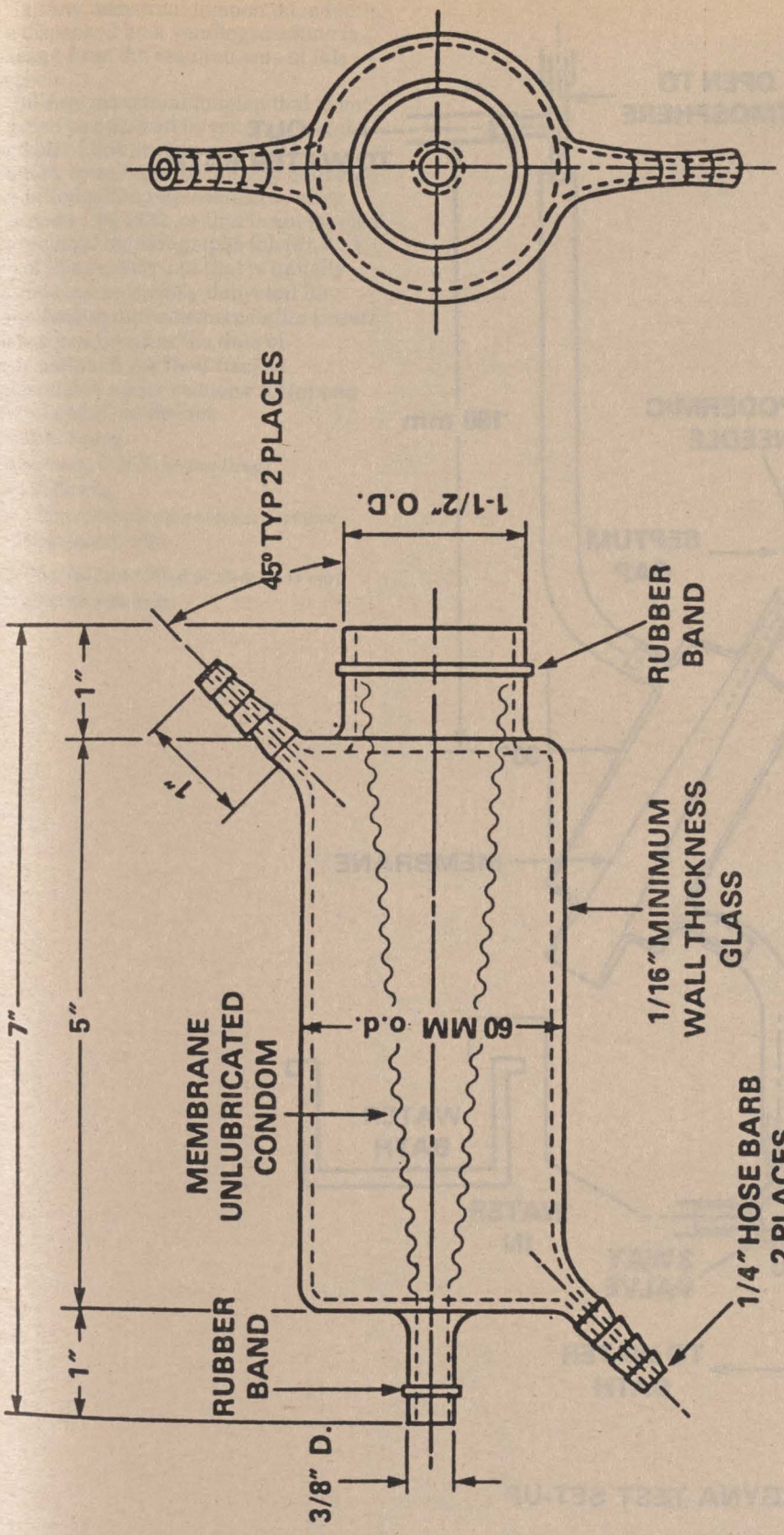

FIGURE 1 — SYNGYNA TEST CHAMBER

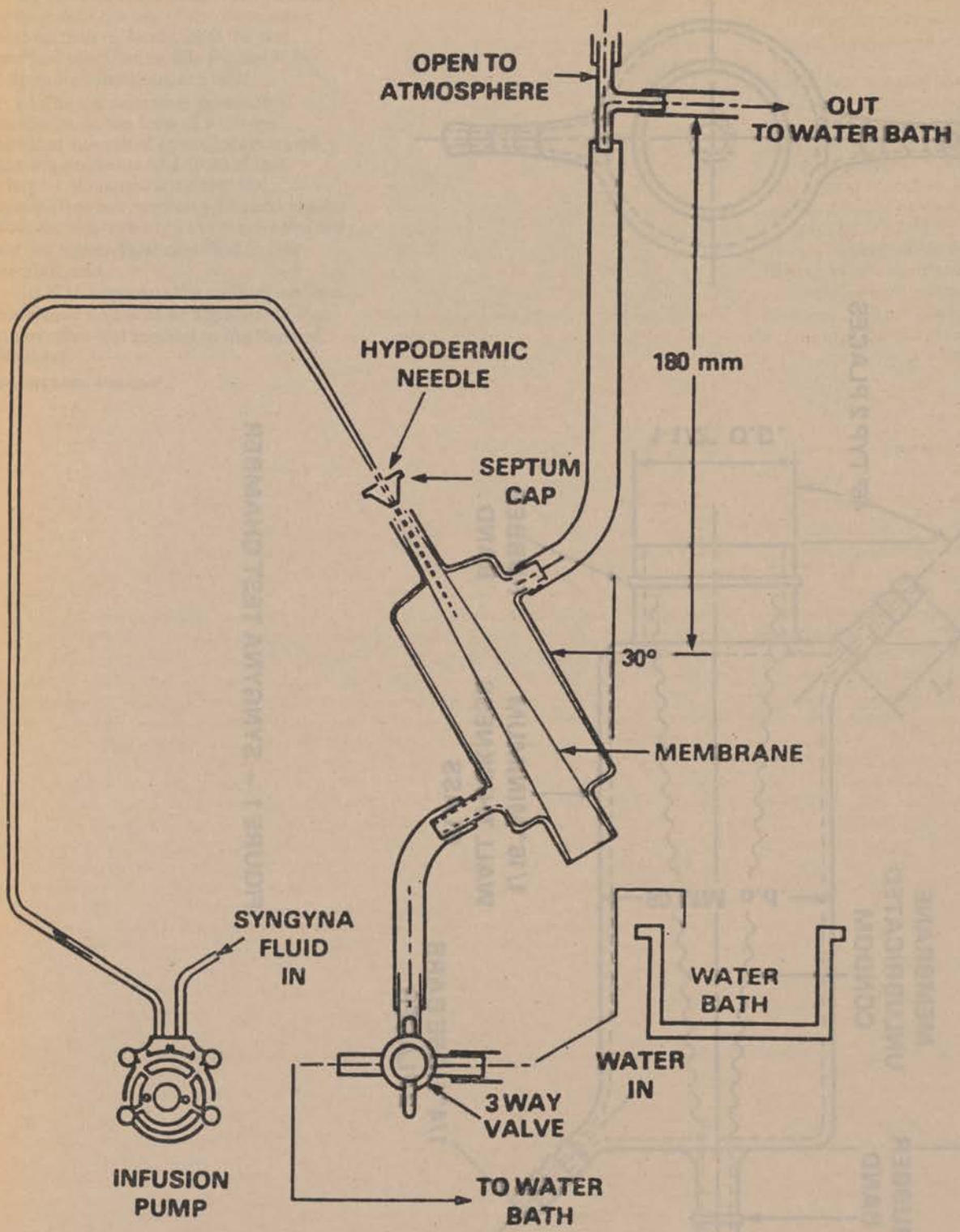

FIGURE 2—SYNGYNA TEST SET-UP

(g) Any menstrual tampon intended to be dispensed by a vending machine is exempt from the requirements of this section.

(h) Any menstrual tampon that is not labeled as required by paragraphs (c) and (d) of this section and that is initially introduced or initially delivered for introduction into commerce after December 20, 1982, or that is not labeled as required by paragraphs (c), (d), and (e) of this section and that is initially introduced or initially delivered for introduction into commerce after (insert date 6 months after the date of publication of the final rule), is misbranded under sections 201(n) and 502(a) and (f) of the act.

Frank E. Young,

Commissioner of Food and Drugs.

Otis R. Bowen,

Secretary of Health and Human Services.

Dated: June 2, 1988.

[FR Doc. 88-21664 Filed 9-22-88; 8:45 am]

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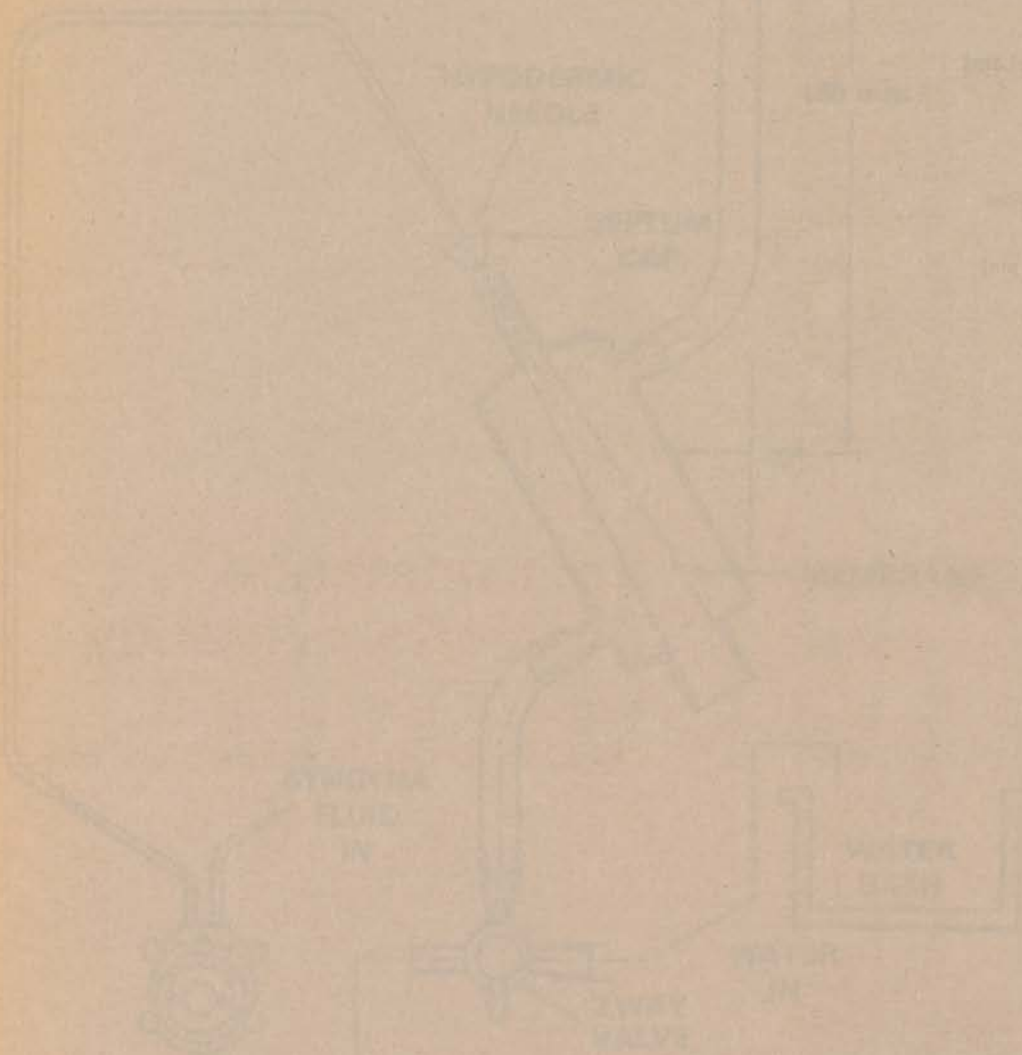

federal register

Friday
September 23, 1988

Part IV

Environmental Protection Agency

40 CFR Part 13
Claims Collection Standards; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 13

[FRL-3364-9]

Claims Collections Standards

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is revising its regulation at 40 Code of Federal Regulations, Chapter I by adding a new Part 13. This revision is necessary to implement the Debt Collection Act of 1982 (Pub. L. 97–365), the Federal guidelines for Agency debt collection issued by the Department of Justice and the General Accounting Office (4 CFR 101 *et seq.*) and the guidelines of the Office of Personnel Management (5 CFR 550 *et seq.*) on offsets against employee salaries.

This regulation will enhance EPA's ability to collect its debts and reduce delinquencies by providing guidance to its officers and employees on the procedures authorized by the Debt Collection Act of 1982.

DATE: October 24, 1988.

FOR FURTHER INFORMATION CONTACT: Ray E. Spears, EPA Claims Officer, at (202) 382–4548.

SUPPLEMENTARY INFORMATION: On August 25, 1987, the U.S. Environmental Protection Agency (EPA) requested public comment on its proposed claims collection standards. We received comments from one commenter. The commenter questioned whether EPA continues to have "common law authority" to assess interest on delinquent debts owned by State and local governments. We reviewed the Government's position on the issue of the continued validity of common law authority for interest assessments. We have concluded that continued assessment of interest on State and local governments is consistent with the United States' position that the Debt Collection Act did not abrogate the assessment of interest on outstanding debts authorized outside of that statute.

The commenter also raised several questions concerning the relationship of the claims collection standards to EPA's procedures for grant resolutions under 40 CFR Part 30. The claims collection standards control EPA's collection, compromise, suspension, termination, offset and referral of delinquent debts. The regulation clearly states at § 13.4 that it does not supersede or require omission or duplication of administrative proceedings required by contract, statute, regulation or other Agency procedures. As such, the regulation does not alter the grant requirements of Part 30. Accordingly, we do not find that further clarification of the regulation is needed.

Lastly, the commenter suggests that the concept of retroactive application precludes applying the procedures of the regulation to existing grants. As indicated above, the regulation controls EPA's collection and resolution of its debts, it does not address either the rights or available procedures of grantees under grant agreements; such rights and procedures are defined by EPA's grant regulations and the grant agreement itself. Accordingly, the issue of retroactive application of the regulation to grantees is not relevant and changes to the regulation have not been made.

The Administrator has determined that this final regulation is not a "major rule" as defined in Executive Order 12291, dated February 17, 1981, because it will not result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with Foreign-based enterprises in domestic or export markets.

The Administrator further certifies that this regulation will not have a significant economic impact on a substantial number of small entities, including small business, small organizational units and small governmental jurisdictions.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB and any EPA response to those comments are in the public docket for this rule making.

List of Subjects in 40 CFR Part 13

Claims, Government employees, Wages.

Dated: September 15, 1988.

Lee M. Thomas,

Administrator.

For the reasons set forth in the preamble, 40 CFR Chapter I is amended by adding a new Part 13 to read as follows:

PART 13—CLAIMS COLLECTION STANDARDS

Subpart A—General

Sec.

Subpart B—Collection

Subpart C—Administrative Offset

Subpart D—Compromise of Debts

Subpart E—Suspension of Collection Action

Subpart F—Termination of Debts

Subpart G—Referrals

Authority: Federal Claims Collection Act of 1966, as amended, 31 U.S.C. 3711 *et seq.*; the Federal Claims Collection Standards, 4 CFR Parts 101–105; 5 U.S.C. 552a, 5512, and 5514.

Subpart A—General

§ 13.1 Purpose and scope.

This regulation prescribes standards and procedures for the Environmental Protection Agency's (EPA's) collection and disposal of debts. These standards and procedures are applicable to all debts for which a statute, regulation or

contract does not prescribe different standards or procedures. This regulation covers EPA's collection, compromise, suspension, termination, and referral of debts.

§ 13.2 Definitions.

(a) "Debt" means an amount owed to the United States from sources which include loans insured or guaranteed by the United States and all other amounts due the United States from fees, grants, contracts, leases, rents, royalties, services, sales of real or personal property, overpayments, fines, penalties, damages, interest, forfeitures (except those arising under the Uniform Code of Military Justice), and all other similar sources. As used in this regulation, the terms "debt" and "claim" are synonymous.

(b) "Delinquent debt" means any debt which has not been paid by the date specified by the Government for payment or which has not been satisfied in accordance with a repayment agreement.

(c) "Debtor" means an individual, organization, association, corporation, or a State or local government indebted to the United States or a person or entity with legal responsibility for assuming the debtor's obligation.

(d) "Agency" means the United States Environmental Protection Agency.

(e) "Administrator" means the Administrator of EPA or an EPA employee or official designated to act on the Administrator's behalf.

(f) "Administrative offset" means the withholding of money payable by the United States to, or held by the United States for, a person to satisfy a debt the person owes the Government.

(g) "Creditor agency" means the Federal agency to which the debt is owed.

(h) "Disposable pay" means that part of current basic pay, special pay, incentive pay, retired pay, retainer pay, or in the case of an employee not entitled to basic pay, other authorized pay remaining after the deduction of any amount described in 5 CFR 581.105 (b) through (f). These deductions include, but are not limited to: Social security withholdings; Federal, State and local tax withholdings; health insurance premiums; retirement contributions; and life insurance premiums.

(i) "Employee" means a current employee of the Federal Government including a current member of the Armed Forces.

(j) "Person" means an individual, firm, partnership, corporation, association and, except for purposes of administrative offsets under Subpart C and interest, penalty and administrative costs under Subpart B of this regulation, includes State and local governments and Indian tribes and components of tribal governments.

(k) "Employee salary offset" means the administrative collection of a debt by deductions at one or more officially established pay intervals from the current pay account of an employee without the employee's consent.

(l) "Waiver" means the cancellation, remission, forgiveness or non-recovery of a debt or debt-related charge as permitted or required by law.

§ 13.3 Interagency claims.

This regulation does not apply to debts owed EPA by other Federal agencies. Such debts will be resolved by negotiation between the agencies or by referral to the General Accounting Office (GAO).

§ 13.4 Other remedies.

(a) This regulation does not supersede or require omission or duplication of administrative proceedings required by contract, statute, regulation or other Agency procedures, *e.g.*, resolution of audit findings under grants or contracts, informal grant appeals, formal appeals, or review under a procurement contract.

(b) The remedies and sanctions available to the Agency under this regulation for collecting debts are not intended to be exclusive. The Agency may impose, where authorized, other appropriate sanctions upon a debtor for inexcusable, prolonged or repeated failure to pay a debt. For example, the Agency may stop doing business with a grantee, contractor, borrower or lender; convert the method of payment under a grant or contract from an advance payment to a reimbursement method; or revoke a grantee's or contractor's letter-of-credit.

§ 13.5 Claims involving criminal activities or misconduct.

(a) The Administrator will refer cases of suspected criminal activity or misconduct to the EPA Office of Inspector General. That office has the responsibility for investigating or referring the matter, where appropriate, to the Department of Justice (DOJ), and/or returning it to the Administrator for further actions. Examples of activities which should be referred are matters involving fraud, anti-trust violations, embezzlement, theft, false claims or misyse of Government money or property.

(b) The Administrator will not administratively compromise, terminate, suspend or otherwise dispose of debts involving criminal activity or misconduct without the approval of DOJ.

§ 13.6 Subdivision of claims not authorized.

A claim will not be subdivided to avoid the $20,000 limit on the Agency's authority to compromise, suspend, or terminate a debt. A debtor's liability arising from a particular transaction or contract is a single claim.

§ 13.7 Omission not a defense.

Failure by the Administrator to comply with any provision of this regulation is not available to a debtor as a defense against payment of a debt.

Subpart B—Collection

§ 13.8 Collection rule.

(a) The Administrator takes action to collect all debts owed the United States arising out of EPA activities and to reduce debt delinquencies. Collection actions may include sending written demands to the debtor's last known address. Written demand may be preceded by other appropriate action, including immediate referral to DOJ for litigation, when such action is necessary to protect the Government's interest. The Administrator may contact the debtor by telephone, in person and/or in writing to demand prompt payment, to discuss the debtor's position regarding the existence, amount or repayment of the debt, to inform the debtor of its rights (*e.g.*, to apply for waiver of the indebtedness or to have an administrative review) and of the basis for the debt and the consequences of nonpayment or delay in payment.

(b) The Administrator maintains an administrative file for each debt and/or debtor which documents the basis for the debt, all administrative collection actions regarding the debt (including communications to and from the debtor) and its final disposition. Information from a debt file relating to an individual may be disclosed only for purposes which are consistent with this regulation, the Privacy Act of 1974 and other applicable law.

§13.9 Initial notice.

(a) When the Administrator determines that a debt is owed EPA, he provides a written initial notice to the debtor. Unless otherwise provided by agreement, contract or order, the initial notice informs the debtor:

(1) Of the amount, nature and basis of the debt;

(2) That payment is due immediately upon receipt of the notice;

(3) That the debt is considered delinquent if it is not paid within 30

days of the date mailed or hand-delivered;

(4) That interest charges and, except for State and local governments and Indian tribes, penalty charges and administrative costs may be assessed against a delinquent debt;

(5) Of any rights available to the debtor to dispute the validity of the debt or to have recovery of the debt waived (citing the available review or waiver authority, the conditions for review or waiver, and the effects of the review or waiver request on the collection of the debt), and of the possibility of assessment of interest, penalty and administrative costs; and

(6) The address, telephone number and name of the person available to discuss the debt.

(b) EPA will respond promptly to communications from the debtor. Response generally will be within 20 days of receipt of communication from the debtor.

(c) Subsequent demand letters also will advise the debtor of any interest, penalty or administrative costs which have been assessed and will advise the debtor that the debt may be referred to a credit reporting agency (see § 13.14), a collection agency (see § 13.13) or to DOJ (see § 13.33) if it is not paid.

§13.10 Aggressive collection actions; documentation.

(a) EPA takes actions and effective follow-up on a timely basis to collect all claims of the United States for money and property arising out of EPA's activities. EPA cooperates with other Federal agencies in their debt collection activities.

(b) All administrative collection actions are documented in the claim file, and the bases for any compromise, termination or suspension of collection actions is set out in detail. This documentation, including the Claims Collection Litigation Report required § 13.33, is retained in the appropriate debt file.

§13.11 Interest, penalty and administrative costs.

(a) *Interest*

EPA will assess interest on all delinquent debts unless prohibited by statute, regulation or contract.

(1) Interest begins to accrue on all debts from the date of the initial notice to the debtor. EPA will not recover interest where the debt is paid within 30 days of the date of the notice. EPA will assess an annual rate of interest that is equal to the rate of the current value of funds to the United States Treasury (*i.e.*, the Treasury tax and loan account rate) as prescribed and published by the Secretary of the Treasury in the **Federal Register** and the Treasury Fiscal Requirements Manual Bulletins, unless a different rate is necessary to protect the interest of the Government. EPA will notify the debtor of the basis for its finding that a different rate is necessary to protect the interest of the Government.

(2) The Administrator may extend the 30-day period for payment where he determines that such action is in the best interest of the Government. A decision to extend or not to extend the payment period is final and is not subject to further review.

(3) The rate of interest, as initially assessed, remains fixed for the duration of the indebtedness. If a debtor defaults on a repayment agreement, interest may be set at the Treasury rate in effect on the date a new agreement is executed.

(4) Interest will not be assessed on interest charges, administrative costs or later payment penalties. However, where a debtor defaults on a previous repayment agreement and interest, administrative costs and penalties charges have been waived under the defaulted agreement, these charges can be reinstated and added to the debt principal under any new agreement and interest charged on the entire amount of the debt.

(b) *Administrative costs of collecting overdue debts.* The costs of the Agency's administrative handling of overdue debts, based on either actual or average cost incurred, will be charged on all debts except those owed by State and local governments and Indian tribes. These costs include both direct and indirect costs. Administrative costs will be assessed monthly throughout the period the debt is overdue except as provided by § 13.12.

(c) *Penalties.* As provided by 31 U.S.C. 3717(e)(2), a penalty charge will be assessed on all debts, except those owned by State and local governments and Indian tribes, more than 90 days delinquent. The penalty charge will be at a rate not to exceed 6% per annum and will be assessed monthly.

(d) *Allocation of payments.* A partial payment by a debtor will be applied first to outstanding administrative costs, second to penalty assessments, third to accrued interest and then to the outstanding debt principal.

(e) *Waiver.* (1) The Administrator may (without regard to the amount of the debt) waive collection of all or part of accrued interest, penalty or administrative costs, where he determines that—

(i) Waiver is justified under the criteria of § 13.25;

(ii) The debt or the charges resulted from the Agency's error, action or inaction, and without fault by the debtor; or

(iii) Collection of these charges would be against equity and good conscience or not in the best interest of the United States.

(2) A decision to waive interest, penalty charges or administrative costs may be made at any time prior to payment of a debt. However, where these charges have been collected prior to the waiver decision, they will not be refunded. The Administrator's decision to waive or not waive collection of these charges is a final agency action.

§ 13.12 Interest and charges pending waiver or review.

Interest, penalty charges and administrative costs will continue to accrue on a debt during administrative appeal, either formal or informal, and during waiver consideration by the Agency; *except,* that interest, penalty charges and administrative costs will not be assessed where a statute or a regulation specifically prohibits collection of the debt during the period of the administrative appeal or the Agency review.

§ 13.13 Contracting for collection services.

EPA will use private collection services where it determines that their use is in the best interest of the Government. Where EPA determines that there is a need to contract for collection services it will—

(a) Retain sole authority to resolve any dispute by the debtor of the validity of the debt, to compromise the debt, to suspend or terminate collection action, to refer the debt to DOJ for litigation, and to take any other action under this part which does not result in full collection of the debt;

(b) Require the contractor to comply with the Privacy Act of 1974, as amended, to the extent specified in 5 U.S.C. 552a(m), with applicable Federal and State laws pertaining to debt collection practices (*e.g.*, the Fair Debt Collection Practices Act (15 U.S.C. 1692 *et seq.*)), and with applicable regulations of the Internal Revenue Service;

(c) Require the contractor to account accurately and fully for all amounts collected; and

(d) Require the contractor to provide to EPA, upon request, all data and reports contained in its files relating to its collection actions on a debt.

§ 13.14 Use of credit reporting agencies.

EPA reports delinquent debts to appropriate credit reporting agencies.

(a) EPA provides the following information to the reporting agencies:

(1) A statement that the claim is valid and is overdue;

(2) The name, address, taxpayer identification number and any other information necessary to establish the identity of the debtor;

(3) The amount, status and history of the debt; and

(4) The program or pertinent activity under which the debt arose.

(b) Before disclosing debt information, EPA will:

(1) Take reasonable action to locate the debtor if a current address is not available; and

(2) If a current address is available, notify the debtor by certified mail, return receipt requested, that:

(i) The designated EPA official has reviewed the claim and has determined that it is valid and overdue;

(ii) That within 60 days EPA intends to disclose to a credit reporting agency the information authorized for disclosure by this subsection; and

(iii) The debtor can request a complete explanation of the claim, can dispute the information in EPA's records concerning the claim, and can file for an administrative review, waiver or reconsideration of the claim, where applicable.

(c) Before information is submitted to a credit reporting agency, EPA will provide a written statement to the reporting agency that all required actions have been taken. Additionally, EPA will, thereafter, ensure that the credit reporting agency is promptly informed of any substantive change in the conditions or amounts of the debt, and promptly verify or correct information relevant to the claim.

(d) If a debtor disputes the validity of the debt, the credit reporting agency will refer the matter to the appropriate EPA official. The credit reporting agency will exclude the debt from its reports until EPA certifies in writing that the debt is valid.

§ 13.15 Taxpayer information.

(a) The Administrator may obtain a debtor's current mailing address from the Internal Revenue Service.

(b) Addresses obtained from the Internal Revenue Service will be used by the Agency, its officers, employees, agents or contractors and other Federal agencies only to collect or dispose of debts, and may be disclosed to credit reporting agencies only for the purpose of their use in preparing a commercial credit report on the taxpayer for use by EPA.

§ 13.16 Liquidation of collateral.

Where the Administrator holds a security instrument with a power of sale or has physical possession of collateral, he may liquidate the security or collateral and apply the proceeds to the overdue debt. EPA will exercise this right where the debtor fails to pay within a reasonable time after demand, unless the cost of disposing of the collateral is disproportionate to its value or special circumstances require judicial foreclosure. However, collection from other businesses, including liquidation of security or collateral, is not a prerequisite to requiring payment by a surety or insurance company unless expressly required by contract or statute. The Administrator will give the debtor reasonable notice of the sale and an accounting of any surplus proceeds and will comply with any other requirements of law or contract.

§ 13.17 Suspension or revocation of license or eligibility.

When collecting statutory penalties, forfeitures, or debts for purposes of enforcement or compelling compliance, the Administrator may suspend or revoke licenses or other privileges for any inexcusable, prolonged or repeated failure of a debtor to pay a claim. Additionally, the Administrator may suspend or disqualify any contractor, lender, broker, borrower, grantee or other debtor from doing business with EPA or engaging in programs EPA sponsors or funds if a debtor fails to pay its debts to the Government within a reasonable time. Debtors will be notified before such action is taken and applicable suspension or debarment procedures will be used. The Administrator will report the failure of any surety to honor its obligations to the Treasury Department for action under 6 U.S.C. 11.

§ 13.18 Installment payments.

(a) Whenever, feasible, and except as otherwise provided by law, debts owed to the United States, together with interest, penalty and administrative costs, as required by § 13.11, will be collected in a single payment. However, where the Administrator determines that a debtor is financially unable to pay the indebtedness in a single payment or that an alternative payment mechanism is in the best interest of the United States, the Administrator may approve repayment of the debt in installments. The debtor has the burden of establishing that it is financially unable to pay the debt in a single payment or that an alternative payment mechanism is warranted. If the Administrator agrees to accept payment by installments, the Administrator may require a debtor to execute a written agreement which specifies all the terms of the repayment arrangement and which contains a provision accelerating the debt in the event of default. The size and frequency of installment payments will bear a reasonable relation to the size of the debt and the debtor's ability to pay. The installment payments will be sufficient in size and frequency to liquidate the debt in not more than 3 years, unless the Administrator determines that a longer period is required. Installment payments of less than $50 per month generally will not be accepted, but may be accepted where the debtor's financial or other circumstances justify. If the debt is unsecured, the Administrator may require the debtor to execute a confess-judgment note with a tax carry-forward and a tax carry-back provision. Where the Administrator secures a confess-judgment note, the Administrator will provide the debtor a written explanation of the consequences of the debtor's signing the note.

(b) If a debtor owes more than one debt and designates how a voluntary installment payment is to be applied among the debts, that designation will be approved if the Administrator determines that the designation is in the best interest of the United States. If the debtor does not designate how the payment is to be applied, the Administrator will apply the payment to the various debts in accordance with the best interest of the United States, paying special attention to applicable statutes of limitations.

§ 13.19 Analysis of costs; automation; prevention of overpayments, delinquencies or defaults.

(a) The Administrator may periodically compare EPA's costs in handling debts with the amounts it collects.

(b) The Administrator may periodically consider the need, feasibility, and cost effectiveness of automated debt collection operations.

(c) The Administrator may establish internal controls to identify the causes of overpayments and delinquencies and may issue procedures to prevent future occurrences of the identified problems.

SUBPART C—Administrative Offset

§ 13.20 Administrative offset of general debts.

This subpart provides for EPA's collection of debts by administrative offset under section 5 of the Debt Collection Act of 1982 (31 U.S.C. 3716), other statutory authorities and the

common law. It does not apply to offsets against employee salaries covered by §§ 13.21, 13.22 and 13.23 of this subpart. EPA will collect debts by administrative offsets where it determines that such collections are feasible and are not otherwise prohibited by statute or contract.

EPA will decide, on a case-by-case basis, whether collection by administrative offset is feasible and that its use furthers and protects the interest of the United States.

(a) *Standards.* (1) The Administrator collects debts by administrative offset it—

(i) The debt is certain in amount;

(ii) Efforts to obtain direct payment from the debtor have been, or would most likely be, unsuccessful or the Administrator and the debtor agree to the offset;

(iii) Offset is not expressly or implicitly prohibited by statute, regulation or contract;

(iv) Offset is cost-effective or has significant deterrent value;

(v) Offset does not substantially impair or defeat program objectives; and

(vi) Offset is best suited to further and protect the Government's interest.

(2) The Administrator may, in determining the method and amount of the offset, consider the financial impact on the debtor.

(b) *Interagency offset.* The Administrator may offset a debt owed to another Federal agency from amounts due or payable by EPA to the debtor, or may request another Federal agency to offset a debt owed to EPA. The Administrator may request the Internal Revenue Service to offset an overdue debt from a Federal income tax refund due a debtor where reasonable attempts to obtain payment have failed. Interagency offsets from employee salaries will be made in accordance with the procedures contained in §§ 13.22 and 13.23.

(c) *Multiple debts.* Where moneys are available for offset against multiple debts of a debtor, it will be applied in accordance with the best interest of the Government as determined by the Administrator on a case-by-case basis.

(d) *Statutory bar to offset.* Administrative offset will not be made more than 10 years after the Government's right to collect the debt first accrued, unless facts material to the Government's right to collect the debt were not known and could not have been known through the exercise of reasonable care by the officer responsible for discovering or collecting the debt. For purposes of offset, the right to collect a debt accrues when the appropriate EPA official determines that a debt exists (e.g., contracting officer, grant award official, etc.), when it is affirmed by an administrative appeal or a court having jurisdiction, or when a debtor defaults on a payment agreement, whichever is latest. An offset occurs when money payable to the debtor is first withheld or when EPA requests offset from money held by another agency.

(e) *Pre-offset notice.* Before initiating offset, the Administrator sends the debtor written notice of:

(1) The basis for and the amount of the debt as well as the Agency's intention to collect the debt by offset if payment or satisfactory response has not been received within 30 days of the notice;

(2) The debtor's right to submit an alternative repayment schedule, to inspect and copy agency records pertaining to the debt, to request review of the determination of indebtedness or to apply for waiver under any available statute or regulation; and

(3) Applicable interest, penalty charges and administrative costs.

(f) *Alternative repayment.* The Administrator may, at the Administrator's discretion, enter into a repayment agreement with the debtor in lieu of offset. In deciding whether to accept payment of the debt by an alternative repayment agreement, the Administrator may consider such factors as the amount of the debt, the length of the proposed repayment period, whether the debtor is willing to sign a confess-judgment note, past Agency dealings with the debtor, documentation submitted by the debtor indicating that an offset will cause undue financial hardship, and the debtor's financial ability to adhere to the terms of a repayment agreement. The Administrator may require financial documentation from the debtor before considering the repayment arrangement.

(g) *Review of administrative determination.* (1) A debt will not be offset while a debtor is seeking either formal or informal review of the validity of the debt under this section or under another statute, regulation or contract. However, interest, penalty and administrative costs will continue to accrue during this period, unless otherwise waived by the Administrator. The Administrator may initiate offset as soon as practical after completion of review or after a debtor waives the opportunity to request review.

(2) The Administrator may administratively offset a debt prior to the completion of a formal or informal review where the determines that:

(i) Failure to take the offset would substantially prejudice EPA's ability to collect the debt; and

(ii) The time before the first offset is to be made does not reasonably permit the completion of the review procedures. (Offsets taken prior to completion of the review process will be followed promptly by the completion of the process. Amounts recovered by offset but later found not to be owed will be refunded promptly.)

(3) The debtor must provide a written request for review of the decision to offset the debt no later than 15 days after the date of the notice of the offset unless a different time is specifically prescribed. The debtor's request must state the basis for the request for review.

(4) The Administrator may grant an extension of time for filing a request for review if the debtor shows good cause for the late filing. A debtor who fails timely to file or to request an extension waives the right to review.

(5) The Administrator will issue, no later than 60 days after the filing of the request, a written final decision based on the evidence, record and applicable law.

§ 13.21 Employee salary offset—general.

(a) *Purpose.* This section establishes EPA's policies and procedures for recovery of debts owed to the United States by installment collection from the current pay account of an employee.

(b) *Scope.* The provisions of this section apply to collection by salary offset under 5 U.S.C. 5514 of debts owed EPA and debts owed to other Federal agencies by EPA employees. This section does not apply to debts owed EPA arising from travel advances under 5 U.S.C. 5705, employee training expenses under 5 U.S.C. 4108 and to other debts where collection by salary offset is explicitly provided for or prohibited by another statute.

(c) *References.* The following statutes and regulations apply to EPA's recovery of debts due the United States by salary offset:

(1) 5 U.S.C. 5514, as amended, governing the installment collection of debts;

(2) 31 U.S.C. 3716, governing the liquidation of debts by administrative offset;

(3) 5 CFR Part 550, Subpart K, setting forth the minimum requirements for executive agency regulations on salary offset; and

(4) 4 CFR Parts 101–105, the Federal Claims Collection Standards.

§ 13.22 Salary offset when EPA is the creditor agency.

(a) *Entitlement to notice, hearing, written response and decision.* (1) Prior to initiating collection action through salary offset, EPA will first provide the employee with the opportunity to pay in full the amount owed, unless such notification will compromise the Government's ultimate ability to collect the debt.

(2) Except as provided in paragraph (b) of this section, each employee from whom the Agency proposes to collect a debt by salary offset under this section is entitled to receive a written notice as described in paragraph (c) of this section.

(3) Each employee owing a debt to the United States which will be collected by salary offset is entitled to request a hearing on the debt. This request must be filed as prescribed in paragraph (d) of this section. The Agency will make appropriate hearing arrangements which are consistent with law and regulations. Where a hearing is held, the employee is entitled to a written decision on the following issues:

(i) The determination of the Agency concerning the existence or amount of the debt; and

(ii) The repayment schedule, if it was not established by written agreement between the employee and the Agency.

(b) *Exceptions to entitlement to notice, hearing, written response and final decision.* The procedural requirements of paragraph (a) of this section are not applicable to any adjustment of pay arising out of an employee's election of coverage or a change in coverage under a Federal benefits program (such as health insurance) requiring periodic deductions from pay, if the amount to be recovered was accumulated over four pay periods or less. However, if the amount to be recovered was accumulated over more than four pay periods the full procedures prescribed under paragraph (d) of this section will be extended to the employee.

(c) *Notification before deductions begin.* Except as provided in paragraph (b) of this section, deductions will not be made unless the employee is first provided with a minimum of 30 calendar days written notice. Notice will be sent by certified mail (return receipt requested), and must include the following:

(1) The Agency's determination that a debt is owed, including the origin, nature, and amount of the debt;

(2) The Agency's intention to collect the debt by means of deductions from the employee's current disposable pay account;

(3) The amount, frequency, proposed beginning date and duration of the intended deductions. (The proposed beginning date for salary offset cannot be earlier than 30 days after the date of notice, unless this would compromise the Government's ultimate ability to resolve the debt);

(4) An explanation of the requirements concerning interest, penalty and administrative costs;

(5) The employee's right to inspect and copy all records relating to the debt or to request and receive a copy of such records;

(6) If not previously provided, the employee's right to enter into a written agreement for a repayment schedule differing from that proposed by the Agency where the terms of the proposed repayment schedule are acceptable to the Agency. (Such an agreement must be in writing and signed by both the employee and the appropriate EPA official and will be included in the employee's personnel file and documented in the EPA payroll system);

(7) The right to a hearing conducted by a hearing official not under the control of the Administrator, if a request is filed;

(8) The method and time for requesting a hearing;

(9) That the filing of a request for hearing within 15 days of receipt of the original notification will stay the assessment of interest, penalty and administrative costs and the commencement of collection proceedings;

(10) That a final decision on the hearing (if requested) will be issued at the earliest practical date, but no later than 60 days after the filing of the request, unless the employee requests and the hearing official grants a delay in the proceedings;

(11) That knowingly false or frivolous statements, representations or evidence may subject the employee to—

(i) Disciplinary procedures under 5 U.S.C. Chapter 75 or any other applicable statutes or regulations;

(ii) Criminal penalties under 18 U.S.C. 286, 287, 1001 and 1002 or other applicable statutory authority; or

(iii) Penalties under the False Claims Act, 31 U.S.C. 3729–3731, or any other applicable statutory authority;

(12) Any other rights and remedies available under statutes or regulations governing the program for which the collection is being made; and

(13) That amounts paid or deducted for the debt, except administrative costs and penalty charges where the entire debt is not waived or terminated, which are later waived or found not owed to the United States will be promptly refunded to the employee.

(d) *Request for hearing.* An employee may request a hearing by filing a written request directly with the Director, Financial Management Division (PM–226F), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The request must state the bases upon which the employee disputes the proposed collection of the debt. The request must be signed by the employee and be received by EPA within 15 days of the employee's receipt of the notification of proposed deductions. The employee should submit in writing all facts, evidence and witnesses which support his/her position to the Director, Financial Management Division, within 15 days of the date of the request for a hearing. The Director, Financial Management Division, will arrange for the services of a hearing official not under the control of the Administrator and will provide the hearing official with all documents relating to the claim.

(e) *Requests for hearing made after time expires.* Late requests for a hearing may be accepted if the employee can show that the delay in filing the request for a hearing was due to circumstances beyond the employee's control.

(f) *Form of hearing, written response and final decision.* (1) Normally, a hearing will consist of the hearing official making a decision based upon a review of the claims file and any materials submitted by the debtor. However, in instances where the hearing official determines that the validity of the debt turns on an issue of veracity or credibility which cannot be resolved through review of documentary evidence, the hearing official at his discretion may afford the debtor an opportunity for an oral hearing. Such oral hearings will consist of an informal conference before a hearing official in which the employee and the Agency will be given the opportunity to present evidence, witnesses and argument. If desired, the employee may be represented by an individual of his/her choice. The Agency shall maintain a summary record of oral hearings provided under these procedures.

(2) Written decisions provided after a request for hearing will, at a minimum, state the facts evidencing the nature and origin of the alleged debt; and the hearing official's analysis, findings and conclusions.

(3) The decision of the hearing official is final and binding on the parties.

(g) *Request for waiver.* In certain instances, an employee may have a statutory right to request a waiver of overpayment of pay or allowances, e.g.,

5 U.S.C. 5584 or 5 U.S.C. 5724(i). When an employee requests waiver consideration under a right authorized by statute, further collection on the debt will be suspended until a final administrative decision is made on the waiver request. However, where it appears that the Government's ability to recover the debt may be adversely affected because of the employee's resignation, termination or other action, suspension of recovery is not required. During the period of the suspension, interest, penalty charges and administrative costs will not be assessed against the debt. The Agency will not duplicate, for purposes of salary offset, any of the procedures already provided the debtor under a request for waiver.

(h) *Method and source of collection.* A debt will be collected in a lump-sum or by installment deductions at established pay intervals from an employee's current pay account, unless the employee and the Agency agree to alternative arrangements for payment. The alternative payment schedule must be in writing, signed by both the employee and the Administrator and will be documented in the Agency's files.

(i) *Limitation on amount of deduction.* The size and frequency of installment deductions generally will bear a reasonable relation to the size of the debt and the employee's ability to pay. However, the amount deducted for any period may not exceed 15 percent of the disposable pay from which the deduction is made, unless the employee has agreed in writing to the deduction of a greater amount. If possible, the installment payments will be in amounts sufficient to liquidate the debt in three years or less. Installment payments of less than $25 normally will be accepted only in the most unusual circumstances.

(j) *Duration of deduction.* If the employee is financially unable to pay a debt in a lump-sum or the amount of the debt exceeds 15 percent of disposable pay, collection will be made in installments. Installment deductions will be made over the period of active duty or employment except as provided in paragraph (a)(1) of this section.

(k) *When deductions may begin.* (1) Deductions to liquidate an employee's debt will begin on the date stated in the Agency's notice of intention to collect from the employee's current pay unless the debt has been repaid or the employee has filed a timely request for hearing on issues for which a hearing is appropriate.

(2) If the employee has filed a timely request for hearing with the Agency, deductions will begin after the hearing official has provided the employee with a final written decision indicating the amount owed the Government. Following the decision by the hearing official, the employee will be given 30 days to repay the amount owed prior to collection through salary offset, unless otherwise provided by the hearing official.

(l) *Liquidation from final check.* If the employee retires, resigns, or the period of employment ends before collection of the debt is completed, the remainder of the debt will be offset from subsequent payments of any nature due the employee (e.g., final salary payment, lump-sum leave, etc.).

(m) *Recovery from other payments due a separated employee.* If the debt cannot be liquidated by offset from any final payment due the employee on the date of separation, EPA will liquidate the debt, where appropriate, by administrative offset from later payments of any kind due the former employee (*e.g.*, retirement pay). Such administrative offset will be taken in accordance with the procedures set forth in § 13.20.

(n) *Employees who transfer to another Federal agency.* If an EPA employee transfers to another Federal agency prior to repaying a debt owed to EPA, the following action will be taken:

(1) The appropriate debt-claim form specified by the Office of Personnel Management (OPM) will be completed and certified to the new paying office by EPA. EPA will certify: That the employee owes a debt; the amount and the basis for the debt; the date on which payment is due; the date the Government's rights to collect the debt first accrued; and that EPA's regulations implementing 5 U.S.C. 5514 have been approved by OPM.

(2) The new paying agency will be advised of the amount which has already been collected, the number of installments and the commencement date for the first installment, if other than the next officially established pay period. EPA will also identify to the new paying agency the actions it has taken and the dates of such actions.

(3) EPA will place or will arrange to have placed in the employee's official personnel file the information required by paragraphs (n) (1) and (2) of this section.

(4) Upon receipt of the official personnel file from EPA, the new paying agency will resume collection from the employee's current pay account and will notify both the employee and EPA of the resumption.

(o) *Interest, penalty and administrative cost.* EPA will assess interest and administrative costs on debts collected under these procedures. The following guidelines apply to the assessment of these costs on debts collected by salary offset:

(1) A processing and handling charge will be assessed on debts collected through salary offset under this section. Where offset begun prior to the employee's receipt of the 30-day written notice of the proposed offset, processing and handling costs will only be assessed after the expiration of the 30-day notice period and after the completion of any hearing requested under paragraph (d) of this section or waiver consideration under paragraph (g) of this section.

(2) Interest will be assessed on all debts not collected within 30 days of either the date of the notice where the employee has not requested a hearing within the allotted time, completion of a hearing pursuant to paragraph (d) of this section, or completion of waiver consideration under paragraph (g) of this section, whichever is later. Interest will continue to accrue during the period of the recovery.

(3) Deductions by salary offset normally begin prior to the time for assessment of a penalty. Therefore, a penalty charge will not be assessed unless deductions occur more than 120 days from the date of notice to the debtor and penalty assessments have not been suspended because of waiver consideration by EPA.

(p) *Non-waiver of right by payment.* An employee's payment under protest of all or any portion of a debt does not waive any rights which the employee may have under either these procedures or any other provision of law.

(q) *Refunds.* EPA will promptly refund to the employee amounts paid or deducted pursuant to this section, the recovery of which is subsequently waived or otherwise found not owing to the United States. Refunds do not bear interest unless specifically authorized by law.

(r) *Time limit for commencing recovery by salary setoff.* EPA will not initiate salary offset to collect a debt more than 10 years after the Government's right to collect the debt first accrued, unless facts material to the right to collect the debt were not known and could not have been known through the exercise of reasonable care by the Government official responsible for discovering and collecting such debts.

§ 13.23 Salary offset when EPA is not the creditor agency.

The requirements below apply when EPA has been requested to collect a debt owed by an EPA employee to another Federal agency.

(a) *Format for the request for recovery.* (1) The creditor agency must complete fully the appropriate claim form specified by OPM.

(2) The creditor agency must certify to EPA on the debt claim form: The fact that the employee owes a debt; the date that the debt first accrued; and that the creditor agency's regulations implementing 5 U.S.C. 5514 have been approved by OPM and send it to the Director, Financial Management Division (PM–226F), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

(3) If the collection is to be made in installments, the creditor agency must also advise EPA of the number of installments to be collected, the amount of each installment, and the commencement date of the first installment, if a date other than the next established pay period.

(4) Unless the employee has consented in writing to the salary deductions or signed a statement acknowledging receipt of the required procedures and this information is attached to the claim form, the creditor agency must indicate the actions it took under its procedures for salary offset and the dates of such actions.

(b) *Processing of the claim by EPA*—(1) *Incomplete claims.* If EPA receives an improperly completed claim form, the claim form and all accompanying material will be returned to the requesting (creditor) agency with notice that OPM procedures must be followed and a properly completed claim form must be received before any salary offset can be taken. The notice should identify specifically what is needed from the requesting agency for the claim to be processed.

(2) *Complete claims.* If the claim procedures in paragraph (a) of this section have been properly completed, deduction will begin on the next established pay period. EPA will not review the merits of the creditor agency's determinations with respect to the amount or validity of the debt as stated in the debt claim form. EPA will not assess a handling or any other related charge to cover the cost of its processing the claim.

(c) *Employees separating from EPA before a debt to another agency is collected*—(1) *Employees separating from Government service.* If an employee begins separation action before EPA collects the total debt due the creditor agency, the following actions will be taken:

(i) To the extent possible, the balance owed the creditor agency will be liquidated from subsequent payments of any nature due the employee from EPA in accordance with § 13.22(1);

(ii) If the total amount of the debt cannot be recovered, EPA will certify to the creditor agency and the employee the total amount of EPA's collection; and

(iii) If EPA is aware that the employee is entitled to payments from the Civil Service Retirement and Disability Fund or other similar payments, it will forward a copy of the claim form to the agency responsible for making such payments as notice that a debt is outstanding. EPA will also send a copy of the claim form to the creditor agency so that it can file a certified claim against the payments.

(2) *Employees who transfer to another Federal agency.* If an EPA employee transfers to another Federal agency before EPA collects the total amount due the creditor agency, the following actions will be taken:

(i) EPA will certify the total amount of the collection made on the debt; and

(ii) The employee's official personnel folder will be sent to the new paying agency. (It is the responsibility of the creditor agency to ensure that the collection is resumed by the new paying agency.)

Subpart D—Compromise of Debts

§ 13.24 General.

EPA may compromise claims for money or property where the claim, exclusive of interest, penalty and administrative costs, does not exceed $20,000. Where the claim exceeds $20,000, the authority to accept the compromise rests solely with DOJ. The Administrator may reject an offer of compromise in any amount. Where the claim exceeds $20,000 and EPA recommends acceptance of a compromise offer, it will refer the claim with its recommendation to DOJ for approval. The referral will be in the form of the Claims Collection Litigation Report (CCLR) and will outline the basis for EPA's recommendation. EPA refers compromise offers for claims in excess of $100,000 to the Commercial Litigation Branch, Civil Division, Department of Justice, Washington, DC 20530, unless otherwise provided by Department of Justice delegations or procedures. EPA refers offers of compromise for claims of $20,000 to $100,000 to the United States Attorney in whose judicial district the debtor can be found. If the Administrator has a debtor's firm written offer for compromise which is substantial in amount but the Administrator is uncertain as to whether the offer should be accepted, he may refer the offer and the supporting data to DOJ or GAO for action.

§ 13.25 Standards for compromise.

(a) EPA may compromise a claim pursuant to this section if EPA cannot collect the full amount because the debtor does not have the financial ability to pay the full amount of the debt within a reasonable time, or the debtor refuses to pay the claim in full and the Government does not have the ability to enforce collection in full within a reasonable time by enforced collection proceedings. In evaluating the acceptability of the offer, the Administrator may consider, among other factors, the following:

(1) *Individual debtors.* (i) Age and health of the debtor;

(ii) Present and potential income;

(iii) Inheritance prospects;

(iv) The possibility that assets have been concealed or improperly transferred by the debtor;

(v) The availability of assets or income which may be realized by enforced collection proceedings; or

(vi) The applicable exemptions available to the debtor under State and Federal law in determining the Government's ability to enforce collection.

(2) *Municipal and quasi-municipal debtors.* (i) The size of the municipality or quasi-municipal entity;

(ii) The availability of current and future resources sufficient to pay the debt (*e.g.*, bonding authority, rate adjustment authority, or taxing authority); or

(iii) The ratio of liabilities (both short and long term) to assets.

(3) *Commercial debtors.* (i) Ratio of assets to liabilities;

(ii) Prospects of future income or losses; or

(iii) The availability of assets or income which may be realized by enforced collection proceedings.

(b) EPA may compromise a claim, or recommend acceptance of a compromise to DOJ, where there is substantial doubt concerning the Government's ability to prove its case in court for the full amount of the claim, either because of the legal issues involved or a bona fide dispute as to the facts. The amount accepted in compromise in such cases will fairly reflect the probability of prevailing on the legal issues involved, considering fully the availability of witnesses and other evidentiary data required to support the Government's claim. In determining the litigative risks involved, EPA will give proportionate weight to the likely amount of court costs and attorney fees the Government

may incur if it is unsuccessful in litigation.

(c) EPA may compromise a claim, or recommend acceptance of a compromise to DOJ, if the cost of collection does not justify the enforced collection of the full amount of the debt. The amount accepted in compromise in such cases may reflect an appropriate discount for the administrative and litigative costs of collection, taking into consideration the time it will take to effect collection. Costs of collection may be a substantial factor in the settlement of small claims, but normally will not carry great weight in the settlement of large claims. In determining whether the cost of collection justifies enforced collection of the full amount, EPA may consider the positive effect that enforced collection of the claim may have on the collection of other similar claims.

(d) Statutory penalties, forfeitures or debts established as an aid to enforcement and to compel compliance may be compromised where the Administrator determines that the Agency's enforcement policy, in terms of deterrence and securing compliance (both present and future), will be adequately served by accepting the offer.

§ 13.26 Payment of compromised claims.

The Administrator normally will not approve a debtor's request to pay a compromised claim in installments. However, where the Administrator determines that payment of a compromise by installments is necessary to effect collection, a debtor's request to pay in installments may be approved. Normally, where installment repayment is approved, the debtor will be required to execute a confess-judgment agreement which accelerates payment of the balance due upon default.

§ 13.27 Joint and several liability.

When two or more debtors are jointly and severally liable, collection action will not be withheld against one debtor until the other or others pay their proportionate share. The amount of a compromise with one debtor is not precedent in determining compromises from other debtors who have been determined to be jointly and severally liable on the claim.

§ 13.28 Execution of releases.

Upon receipt of full payment of a claim or the amount compromised, EPA will prepare and execute a release on behalf of the United States. The release will include a provision which voids the release if it was procured by fraud, misrepresentation, a false claim or by mutual mistake of fact.

Subpart E—Suspension of Collection Action

§ 13.29 Suspension—general.

The Administrator may suspend the Agency's collection actions on a debt where the outstanding debt principal does not exceed $20,000, the Government cannot presently collect or enforce collection of any significant sum from the debtor, the prospects of future collection justify retention of the debt for periodic review and there is no risk of expiration of the statute of limitations during the period of suspension. Additionally, the Administrator may waive the assessment of interest, penalty charges and administrative costs during the period of the suspension. Suspension will be for an established time period and generally will be reviewed at least every six months to ensure the continued propriety of the suspension. DOJ approval is required to suspend debts exceeding $20,000. Unless otherwise provided by DOJ delegations or procedures, the Administrator refers requests for suspension of debts of $20,000 to $100,000 to the United States Attorney in whose district the debtor resides. Debts exceeding $100,000 are referred to the Commercial Litigation Branch, Civil Division, Department of Justice, for approval.

§ 13.30 Standards for suspension.

(a) *Inability to locate debtor.* The Administrator may suspend collection on a debt where he determines that the debtor cannot be located presently but that there is a reasonable belief that the debtor can be located in the future.

(b) *Financial condition of debtor.* The Administrator may suspend collection action on a claim when the debtor owns no substantial equity in real or personal property and is unable to make payment on the claim or effect a compromise but the debtor's future financial prospects justify retention of the claim for periodic review, provided that:

(1) The applicable statute of limitations will not expire during the period of the suspension, can be tolled or has started running anew;

(2) Future collection can be effected by offset, notwithstanding the 10-year statute of limitations for administrative offsets; or

(3) The debtor agrees to pay interest on the debt and suspension is likely to enhance the debtor's ability to fully pay the principal amount of the debt with interest at a later date.

(c) *Request for waiver or administrative review—mandatory.* The Administrator will suspend collection activity where a statute provides for mandatory waiver consideration or administrative review prior to agency collection of a debt. The Administrator will suspend EPA's collection actions during the period provided for the debtor to request review or waiver and during the period of the Agency's evaluation of the request.

(d) *Request for waiver or administrative review—permissive.* The Administrator may suspend collection activities on debts of $20,000 or less during the pendency of a permissive waiver or administrative review where he determines that:

(1) There is a reasonable possibility that waiver will be granted and the debtor may be found not owing the debt (in whole or in part);

(2) The Government's interest is protected, if suspension is granted, by the reasonable assurance that the debt can be recovered if the debtor does not prevail; or

(3) Collection of the debt will cause undue hardship to the debtor.

(e) *Refund barred by statute or regulation.* The Administrator will ordinarily suspend collection action during the pendency of his consideration of a waiver request or administrative review where statute and regulation preclude refund of amounts collected by the Agency should the debtor prevail. The Administrator may decline to suspend collection where he determines that the request for waiver or administrative review is frivolous or was made primarily to delay collection.

Subpart F—Termination of Debts

§ 13.31 Termination—general.

The Administrator may terminate collection actions and write-off debts, including accrued interest, penalty and administrative costs, where the debt principal does not exceed $20,000. If the debt exceeds $20,000, EPA obtains the approval of DOJ in order to terminate further collection actions. Unless otherwise provided for by DOJ regulations or procedures, requests to terminate collection on debts in excess of $100,000 are referred to the Commercial Litigation Branch, Civil Division, Department of Justice, for approval. Debts in excess of $20,000 but $100,000 or less are referred to the United States Attorney in whose judicial district the debtor can be found.

§ 13.32 Standards for termination.

A debt may be terminated where the Administrator determines that:

(a) The Government cannot collect or enforce collection of any significant sum from the debtor, having due regard for available judicial remedies, the debtor's ability to pay, and the exemptions available to the debtor under State and Federal law;

(b) The debtor cannot be located, there is no security remaining to be liquidated, the applicable statute of limitations has expired, and the prospects of collecting by offset are too remote to justify retention of the claim;

(c) The cost of further collection action is likely to exceed the amount recoverable;

(d) The claim is determined to be legally without merit; or

(e) The evidence necessary to prove the claim cannot be produced or the necessary witnesses are unavailable and efforts to induce voluntary payment have failed.

Subpart G—Referrals

§ 13.33 Referrals to the Department of Justice.

(a) *Prompt referral.* The Administrator refers to DOJ for litigation all claims on which aggressive collection actions have been taken but which could not be collected, compromised, suspended or terminated. Referrals are made as early as possible, consistent with aggressive agency collection action, and within the period for bringing a timely suit against the debtor.

(1) Unless otherwise provided by DOJ regulations or procedures, EPA refers for litigation debts of more than $100,000 to the Commercial Litigation Branch, Civil Division, Department of Justice, Washington, DC 20530.

(2) Unless otherwise provided by DOJ regulations or procedures, EPA refers for litigation debts of $100,000 or less to the United States Attorney in whose judicial district the debtor can be found.

(b) *Claims Collection Litigation Report (CCLR).* Unless an exception has been granted by DOJ, the CCLR is used for referrals of all administratively uncollectible claims to DOJ and is used to refer all offers of compromise.

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