and the amendment is effective for the period December 5–11, 1982.

FOR FURTHER INFORMATION CONTACT: William J. Doyle, Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone 202–447–5975.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under Secretary's Memorandum 1512–1 and Executive Order 12291, and has been designated a "non-major" rule. The Deputy Administrator, Agricultural Marketing Service, has determined that this action will not have a significant economic impact on a substantial number of small entities. This action is designed to promote orderly marketing of the California-Arizona lemon crop for the benefit of producers, and will not substantially affect costs for the directly regulated handlers.

This final rule is issued under Marketing Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona. The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The action is based upon the recommendations and information submitted by the Lemon Administrative Committee and upon other available information. It is hereby found that this action will tend to effectuate the declared policy of the act.

This action is consistent with the marketing policy for 1981–82. The marketing policy was recommended by the committee following disusssion at a public meeting on July 6, 1982. The commitee met again publicly on December 7, 1982, at Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended a quantity of lemons deemed advisable to be handled during the specified weeks. The committee reports the demand for lemons is good.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the **Federal Register** (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation and amendment are based and the effective date necessary to effectuate the declared policy of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting, and the amendment relieves restrictions on the handling of lemons. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective times.

List of Subjects in 7 CFR Part 910

Marketing agreements and orders, California, Arizona, Lemons.

PART 910—[AMENDED]

1. Section 910.689 is added as follows:

§ 910.689 Lemon Regulation 389.

The quantity of lemons grown in California and Arizona which may be handled during the period December 12, 1982, through December 18, 1982, is established at 250,000 cartons.

2. Section 910.688 *Lemon Regulation 388* (47 FR 54421) is revised to read as follows:

§ 910.688 Lemon Regulation 388.

The quantity of lemons grown in California and Arizona which may be handled during the period December 5, 1982, through December 11, 1982, is established at 275,000 cartons.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: December 9, 1982.

D. S. Kuryloski,

Acting Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 82-33822 Filed 12-9-82; 11:59 am]

BILLING CODE 3410-02-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 10, 18, 19, 22, 24, 113, 125, 127, 132, 142, and 144

[T.D. 82-204]

Customs Regulations Amendments Relating To Customs Bonded Warehouses

Correction

In the **Federal Register** of Friday, November 19, 1982, on page 52139 there was a correction to FR Doc. 82–29742, which was originally published Monday, November 1, 1982 on page 49355. The heading of the correction document cited only 19 CFR Part 144; however, it should have included references to Parts 10, 18, 19, 22, 24, 113, 125, 127, 132, and 142 also.

BILLING CODE 1505-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Petitions Under Part 10

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority regarding officials who can grant or deny certain petitions submitted under 21 CFR Part 10. The petitions covered by this delegation are those that are submitted requesting either a stay of the effective date or an exemption from the tamper-resistant packaging and labeling requirements for certain over-the-counter (OTC) drug and cosmetic products and contact lens solutions and tablets.

EFFECTIVE DATE: December 10, 1982.

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

SUPPLEMENTARY INFORMATION: FDA is amending § 5.31 (21 CFR 5.31) by adding new paragraph (c) which delegates to certain officials the authority to grant or deny citizen petitions submitted for a stay of the effective date or for an exemption from the tamper-resistant packaging and labeling requirements published in the **Federal Register** of November 5, 1982, for certain OTC drug and cosmetic products (47 FR 50442) and for certain medical devices (47 FR 50452).

The tamper-resistant packaging and labeling requirements for certain OTC drugs were set forth in new § 211.132 (21 CFR 211.132). The requirements for certain cosmetic products were set forth in new § 700.25 (21 CFR 700.25). The requirements for certain medical devices were set forth in new § 800.12 (21 CFR 800.12). Each of these three new sections includes a paragraph regarding the procedure firms should follow if they want to request that a product covered by the rule be exempted from the tamper-resistant packaging and/or labeling requirements. Included as part of the specified procedure is that such a request be submitted in the form of a citizen petition under § 10.30 (21 CFR 10.30). In addition, the preambles to the OTC drug and cosmetic document and the medical device document both recognize that a petition for a stay of the

effective date may be submitted and provide instructions for the submission.

The agency has concluded that the authority to grant or deny such petitions should be delegated to the FDA component responsible for handling the product for which a stay or exemption is being requested. Therefore, § 5.31 is amended to redelegate to: (1) The Director, National Center for Drugs and Biologics (NCDB), and the Director and Deputy Director of the Office of Drugs, NCDB; (2) the Director, Deputy Director, and Associate Director for Compliance of the Bureau of Foods; and (3) the Director and Deputy Director, National Center for Devices and Radiological Health (NCDRH), and the Director and Deputy Director of the Office of Medical Devices, NCDRH, the authority to grant or deny petitions requesting a stay of the effective date or an exemption from the tamper-resistant packaging and labeling requirements set forth in §§ 211.132, 700.25, and 800.12, respectively. Representatives of officials to whom authority is redelegated will work together to ensure consistent and careful decisionmaking on petitions for stays of the effective date of tamper-resistant packaging requirements or for exemptions from the requirements.

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

List of Subjects in 21 CFR Part 5

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

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 5 is amended in § 5.31 by adding new paragraph (c), to read as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

§ 5.31 Petitions under Part 10.

* * * * *

(c) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter for a stay of an effective date or for an exemption from the tamper-resistant packaging and labeling requirements set forth in § 211.132, § 700.25, or § 800.12 of this chapter for certain over-the-counter human drug and cosmetic products and medical devices which relate to the assigned functions of the respective organizations:

(1) The Director, NCDB, and the Director and Deputy Director of the Office of Drugs, NCDB.

(2) The Director, Deputy Director, and Associate Director for Compliance of the Bureau of Foods.

(3) The Director and Deputy Director of the National Center for Devices and Radiological Health (NCDRH), and the Director and Deputy Director of the Office of Medical Devices, NCDRH.

Effective date. This regulation is effective December 10, 1982.

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

Dated: December 2, 1982.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 82-33861 Filed 12-9-82; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 145

[Docket No. 78P-0429]

Canned Pineapple; Amendment of Standards of Identity and Quality; Termination of Stay of Regulation and Establishment of a New Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule; termination of stay and establishment of a new effective date.

SUMMARY: The Food and Drug Administration (FDA) is terminating the stay of the regulation and establishing a new effective date for compliance with all provisions of the amendment to the standards of identity and quality for canned pineapple published in the **Federal Register** of November 24, 1981 (46 FR 57474). That amendment redesignated as "small cubes" or "dice" the style currently referred to as "cubes" or "dice" and provided for an optional style designated as "large cubes". The regulation was stayed to allow FDA to consider issues raised by objections and to decide whether a public hearing was justified. The agency has evaluated the objections and requests for a hearing and concludes that they are not justified. Therefore, this document terminates the stay of the regulation and establishes a new effective date of July 1, 1985.

DATES: Compliance with the final regulation may have begun January 25, 1982, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1985, shall fully comply, in accordance with the August 13, 1982 (47 FR 35185) final rule establishing a new uniform effective date.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 24, 1981 (46 FR 57474), FDA published a final regulation amending the U.S. standards of identity and quality for canned pineapple (21 CFR 145.180 (a) and (b)). The amendment redesignated as "small cubes" or "dice" the style of pineapple previously designated as "cubes" or "dice" and provided for an optional style of canned pineapple designated as "large cubes". The final regulation was based on a petition filed by the Malaysian Pineapple Industry Board, Ministry of Primary Industries of Malaysia, submitted through the Embassy of Malaysia, 2401 Massachusetts Ave. NW., Washington, DC 20008. The agency received two objections and requests for a hearing from the Pineapple Growers Association of Hawaii (PGAH). In the **Federal Register** of March 9, 1982 (47 FR 9997), FDA announced that the effective date of the provisions of this regulation to which objections had been submitted (§ 145.180(a)(2) (viii) and (xi) and (b)(1)(ii)(g)) was stayed while FDA considered whether a hearing had been justified by the objections.

FDA is terminating the previously announced stay because it has concluded that the objections are unpersuasive and the requests for a hearing do not satisfy the requirements for justifying a hearing. The hearing requests are accordingly denied.

Administrative law now firmly establishes that agencies need not grant hearings in circumstances in which it is clear on the basis of the request for hearing that that hearing would be a futile exercise. (See *Costle* v. *Pacific Legal Foundation*, 445 U.S. 198, 213-216 (1980); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 620 (1973).) The instances in which the courts have agreed that agencies have appropriately denied hearings in the face of alleged unresolved factual issues fall into two broad categories. First, persons requesting hearings in some instances have identified factual issues that are not material to the resolution of the matter in dispute. Thus, even if taken as true, the person's factual allegations would not change the outcome of the proceeding. Second, there may be instances in which the parties have failed to show that there is a factual issue to be resolved, by failing to present evidence, in accordance with applicable regulations, that could

possibly lead to a resolution of the dispute in the party's favor.

Here, the principal basis for denial of hearing is the lack of materiality of the issues identified by PGAH for resolution at a hearing. Even if the factual issues identified by PGAH were material, however, there is a second, and totally independent, ground for denial of the hearing. PGAH has failed to identify and come forward with evidence as required by FDA regulations that demonstrates that any issues of fact exist to be heard. This document discusses the lack of materiality of the grounds asserted by PGAH and then addresses the question of the sufficiency of the PGAH submission to justify a hearing even on the factual issues it has identified. Finally, this document addresses the one purely legal issue raised by PGAH's submission.

Failure To Raise Material Factual Issues

The failure to justify a hearing because of failure to raise material issues of fact is exemplified by a recent decision of the United States Court of Appeals for the Ninth Circuit in *Pineapple Growers Association of Hawaii* v. *FDA*, 673 F. 2d 1083 (9th Cir. 1982). There the court upheld FDA's denial of a hearing involving an earlier amendment of the canned pineapple food standards. It noted that FDA conceded the requestor's allegations with respect to several purported issues but found that those allegations, even taken as true, did not alter the agency's final resolution of the issues. FDA regulations specifically contemplated denial of a hearing in such instances. See 21 CFR 12.24(b)(4): "* * * A hearing will not be granted on factual issues that are not determinative with respect to the action requested, e.g., if the Commissioner concludes that the action would be the same even if the factual issue were resolved in the way sought * * *". See also *Processors Council of the California-Arizona Citrus League* v. *FDA*, No. CV 80-3714-MRP (C.D. Cal. September 7, 1982), slip op. at 8 (district court, assuming arguendo that it has jurisdiction to review the matter, holds that denial of hearing on revocation of food standard regulation is justified because objecting party failed to raise material issues of fact).

Each of PGAH's purported factual issues is immaterial to the outcome of this proceeding. In many cases FDA agrees with PGAH's factual assertions. In others, those assertions, even if taken as true, would not change the regulation. Thus, no need for a hearing was demonstrated.

PGAH objected to and requested a hearing on both the "large cubes" style and the "small cubes" or "dice" style, in each case contending that the styles "will not promote honesty and fair dealing in the interest of consumers," the statutory standard (21 U.S.C. 341). PGAH in its Objections and Request for Hearing (PGAH objections) set out its grounds for its objection to the "large cubes" style in two ways. First, PGAH stated certain grounds for objection in textual discussion (PGAH objections at 2–4); then it enumerated specific contentions as to which it said it "is prepared to present specific factual information" (PGAH objections at 4–7). There is some overlap and this notice will attempt to deal with each purported ground.

First, PGAH argued that the "large cubes" style "will serve to mislead consumers by contributing to a proliferation of canned pineapple styles" (PGAH objections at 2), and offered to present evidence to the same effect. Specifically, PGAH stated that it would present evidence that the final standard of identity for canned pineapple provides for 11 separate optional styles, stating that that was 5* more styles than provided for in any other canned food standard, and that none of the standards for canned grapefruit, peaches, or pears provides for more than 7 styles of pack (PGAH objections at 7).

FDA does not disagree that the addition of this new style pack will provide for 11 separate optional styles of canned pineapple. It is also true that, at the time when PGAH submitted its objections, the standards for canned grapefruit, peaches, or pears did not provide for more than 7 styles. (An additional eighth style of canned peaches, "chunky", has been established since the time of the objections (see the **Federal Register** of January 15, 1982 (47 FR 2311)).) It would, however, make no difference to this proceeding if the 11 pineapple styles were 4 or 5 more than the number in any other canned fruit standard.

It should be noted that PGAH has itself sought amendment of the canned pineapple standards to provide for up to nine styles of pack. If 9 styles of pack are consistent with the statute's requirements, as PGAH has asserted, and if 10 styles of pack are consistent with that requirement, as the Ninth Circuit has ruled in *Pineapple Growers Association of Hawaii* v. *FDA, supra*, it is implausible that 11 styles of pack, on the other hand, will impermissibly confuse consumers. Just as it did in denying a hearing on a similar objection to the addition of the tenth ("pieces") style to the canned pineapple standard, FDA here believes that the proper label declarations of each style will inform consumers about the pineapple product they are buying and will, therefore, promote honesty and fair dealing in the consumer's interest. The number of permissible styles does not change that conclusion.

PGAH argued that the "large cubes" style will mislead consumers by employing a label term, i.e., "cubes", exclusively associated with small pineapple units for over 30 years (PGAH objections at 2), and, in a similar vein, offered to prove that, since the 1940's, United States consumers have associated the term "cubes" exclusively with very small pineapple units (i.e., with the preamendment style of "cubes") (PGAH objections at 6) and the term "chunks" with bite size units (PGAH objections at 6). PGAH stated that it would present evidence that FDA in the 1951 hearing that led to the preamendment standard concluded that the term "cubes" was associated with small units and the term "chunks" was "widely preferred" for bite sized units (PGAH objections at 6). Similarly, PGAH offered to present specific factual information that the "large cubes" canned pineapple style has not been sold in the United States, that United States consumers are not familar with the style and that they would not discern a distinction between "large cubes" and "chunks" or between "large cubes" and "small cubes" (PGAH objections at 6).

Each of these arguments is a variation on the simple assertion that the new style is in fact new. As the Ninth Circuit said when PGAH made a similar argument with respect to the amendment allowing "pieces" or "irregular pieces" as a style within the standard, "if consumer unfamiliarity with a new food standard were sufficient to preclude its authorization, American consumers would be forever barred from the opportunity to become acquainted with any new product or product style. This simply cannot be said to be in the consumer's best interest." *Pineapple Growers Association of Hawaii* v. *FDA, supra*, 673 F. 2d at 1086. Certainly it is true that consumers are not now familiar with the "large cubes" style. Similarly, to the extent that consumers are familiar with canned pineapple styles at all, they are now familiar with the preamendment styles. If the amendment in question is implemented, however, it is fair to

* PGAH probably meant to say that 11 separate optional styles for canned pineapple was *4* more styles than are provided for in any other canned food standard.

conclude that consumers will become familiar with what the new styles designate.

PGAH argued that the "large cubes" style would confuse consumers by permitting the same pineapple product to be offered for sale under two different names (i.e., "chunks" and "large cubes") (PGAH objections at 2), and offered to present specific factual information that the cubes that the Malaysians seek to market may come within the style for "chunks" in the preamendment standard (PGAH objections at 5). That state of affairs is said to be a departure from the established format of mutually exclusive styles in canned fruit standards and thus to be not in the interest of the United States consumers (PGAH objections at 5).

Even accepting PGAH's factual assertions as true, as FDA did in issuing the final rule (46 FR 57474), those assertions do not undercut the justification or need for the "large cubes" style. As the preamble to the final rule stated, the products that would be labeled as "large cubes" are different from the products that are normally marketed in this country under the "chunks" designation (PGAH objections at 5). As PGAH does not, and cannot, deny, "chunks" as marketed in the United States have two curved and four planar surfaces, two of the opposing planar surfaces being not parallel. "Large cubes", on the other hand, are cube shaped, i.e., have six planar surfaces.

There is no requirement in the law that prohibits FDA from setting a standard defining styles which are not mutually exclusive. For consistency with other regulations, however, FDA is proposing elsewhere in this issue of the **Federal Register** to amend the standard of identity for canned pineapple to make clear that those products which come within the "large cubes" definition are not included as "chunks". That action is consistent with other designations of styles that make each style mutually exclusive from each other. See, e.g., 21 CFR 145.180(a)(2)(ix) (defining "pieces" or "irregular pieces" as "consisting of irregular shapes and sizes not identifiable as a specific style and [stating that this style] *does not include chunks*" (emphasis added)). Thus, the request for hearing on this assertion is denied because FDA does not dispute PGAH's allegation and there is thus nothing to hear. The objection itself does not suggest a need to withdraw the "large cubes" amendment because mutual exclusivity is not an absolute requirement for food standard styles and, in any case, FDA is amending the "chunks" style to exclude "large cubes".

PGAH also offered to present factual information to the effect that the Malaysian product does not consist of reasonably uniform cube-shaped units of canned pineapple (PGAH objections at 3 and 5). PGAH argued that a sample of the Malaysian pineapple analyzed by FDA was made up of pineapple pieces that were neither cube-shaped nor uniform in size.

The definition of the style does not require absolute uniformity; rather, the pieces must be "reasonably" uniform. Similarly, "cube-shaped" does not require each piece to be a "perfect cube". If PGAH is simply asserting that the hand-cut Malaysian cubes do not approach perfection in either uniformity or shape, FDA concedes that point but finds it irrelevant. The Malaysian pineapple would still conform to the "large cubes" style.

If PGAH is asserting that there will be no product at all marketed in this country that will comply with the "large cubes" definition as articulated, that fact would be "material" to the question whether there should be a "large cubes" style. If that is PGAH's assertion, however, FDA regards that assertion as frivolous. The Malaysian petitioner sought the style specifically to cover its particular product. If, after the regulation establishing this style becomes effective, products are marketed under that style that do not comply with it, those products would be misbranded within the meaning of 21 U.S.C. 343(g)(1) and 341. There is thus a clear impetus for the Malaysian petitioner to assure that the "large cubes" style accurately describes its product.

FDA analyzed the Malaysian cubes on two separate occasions. On the first (on June 19, 1978), the dimensions were found to range from $^{1}/_{16}$ and $^{1}/_{8}$ inch. The second analysis (on Feb. 26, 1981) found similar dimensions $^{1}/_{16}$ to $^{1}/_{8}$ inch, with most cubes having dimensions of $^{1}/_{16}$ and $^{1}/_{8}$ inch). FDA analysts concluded that the Malaysian cubes appear to have a "uniform size and shape" and the product consists of "nearly perfect cubes." (The two FDA analyses are part of the record in the docket of this proceeding.) The product analyzed also fits the dimensions of the style and therefore complies with the "large cubes" style in the standard. Thus, if PGAH is contending that there will be no product that will conform to the "large cubes" style, PGAH has failed to identify or present factual information to justify a hearing on that assertion. See discussion below.

PGAH argued that the "large cubes" style will mislead consumers because it deviates from the Codex Recommended International Standard for Canned Pineapple (PGAH objections at 2, 6–7).

FDA agrees that the "large cubes" style is not a Codex style. As a general policy, FDA does, as PGAH asserts, adopt Codex standards where practicable and agrees that, in general, utilization of such standards is in the public interest. Yet it is clear that the absence of an international Codex standard for "large cubes" will have little or no effect on consumer understanding of that term in the United States. The effect, if any, is on international trade, an issue whose legal significance is discussed below.

PGAH also offered to present factual information that the "large cubes" style, by enlarging the number of permitted canned pineapple styles, will increase the cost of distribution, inventory control, and supermarket shelving, thereby raising the price of canned pineapple products to the consumer's detriment (PGAH objections at 7). This same argument was made by PGAH with respect to the addition of the "pieces" or "irregular pieces" style of pack to the pineapple standard reviewed in the Ninth Circuit case.

Even if it were correct that adding this additional style to the canned pineapple standard would increase certain costs, that fact would not be material to the question whether the style should be permitted. No manufacturer is obligated to market the "large cubes" style, no merchandiser is required to sell it, and no consumer is obligated to buy that style. Thus, any additional cost associated with the new style will simply reflect a business decision of manufacturers and merchandisers that the style is worth marketing and a personal decision by consumers that the style is sufficiently attractive to warrant purchase and consumption.

PGAH objected to the redesignation of the "cubes" or "dice" style as "small cubes" or "dice" on the grounds that, because PGAH says the "large cubes" style is unnecessary, there is no justification for the addition of the adjective "small" to the designation of the "small cubes" or "dice" style (PGAH objections at 8).

As discussed above, the agency has concluded that none of the grounds advanced by PGAH on the question of the propriety of the "large cubes" style justifies a hearing on that issue. Accordingly, those grounds do not support the hearing request with respect to "small cubes" either.

In addition, PGAH stated that it would present specific factual evidence to show that consistent industry practice has established a strong consumer expectation that the "cubes" style of canned pineapple contains very small units and that, thus, the change in the name of that style to "small cubes" will generate consumer confusion (PGAH objection at 8).

This is simply a restatement of the argument, made with respect to "large cubes", that American consumers are not familiar with a style designation that is new. As discussed above, that argument, if accepted, could mean that there would never be any new styles of pack. That outcome is not consistent with the statute's requirements, as the Ninth Circuit held.

PGAH also noted, as a ground for its request for hearing concerning the "small cubes" or "dice" style, that the Codex standard for canned pineapple provides for only one size of pineapple cubes.

As discussed above, the Codex standard is not determinative of what is appropriate for American consumers.

Failure To Identify Factual Evidence

The Supreme Court has recently reaffirmed the validity of a hearing denial based on failure to proffer evidence justifying a hearing. In *Costle* v. *Pacific Legal Foundation, supra,* 445 U.S. at 214–215, the Court emphasized that an agency may, within its discretion, promulgate rules that "require an applicant who seeks a hearing to meet a threshold burden of tendering evidence suggesting the need for a hearing." Consistent with that holding, FDA has placed upon a person seeking an evidentiary hearing an obligation to identify specifically reliable evidence upon which a factual issue stated by that person may be resolved (21 CFR 12.24(b)(2)) and a further obligation to submit data and information which, if established at the hearing, would be adequate to justify resolution of the factual issue in the way sought by the person requesting the hearing (21 CFR 12.24(b)(3)).

PGAH's objections and request for a hearing are a nine page document signed by counsel. With one exception noted below, no evidence is specifically identified for any of the propositions argued by PGAH. As FDA regulations state, "a hearing will not be granted on the basis of mere allegations or denials or general descriptions and contentions" (21 CFR 12.24(b)(2)). That, however, is all that PGAH has provided here. Thus, even if PGAH in its request for a hearing had made factual assertions that were material to the agency's determination, as it has not, those factual issues would not require a hearing. PGAH has simply failed to meet its burden to present evidence suggesting that those factual issues are genuine and warrant a hearing.

In the one place at which PGAH has pointed to specific factual evidence, that evidence directly contradicts PGAH's assertion about it. PGAH refers to a sample of Malaysian pineapple cubes received and analyzed by FDA that PGAH says "demonstrated that the units are neither cube-shaped nor uniform in size" (PGAH objections at 5). As noted above, FDA analysis of that sample disproves that assertion. PGAH has not suggested that the analyst who recorded measurements of the analyzed cubes did not perform the measurements competently or did not record those measurements truthfully. Thus, PGAH's assertion about this evidence is, at best, an argument that a different inference (i.e., that the pieces are not "reasonably uniform" and "cube shaped") should be drawn from established fact (the dimensions of the pieces) than the agency has drawn. No hearing is required in such circumstances. (See *Anti-Defamation League of B'nai B'rith* v. *FCC,* 403 F. 2d 169, 171 (D.C. Cir. 1968), *cert. denied,* 394 U.S. 930 (1969).)

Legal Issue

PGAH makes one assertion that is clearly legal rather than factual. It points to FDA's conclusion, in the preamble to the final regulation, that this regulation would facilitate international trade (PGAH objections at 3–4). That conclusion, PGAH argued, was an improper basis for the regulation. FDA's conclusion that adoption of the amended standard would facilitate international trade was, however, not a predicate for its determination that the standard satisfied the criteria set out in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). As is obvious, it is possible for more than one version of a food standard to satisfy those statutory criteria. In choosing among the different potential versions, FDA may take into account the effect of its choice upon international trade and, consistent with the congressional statement of purpose in the Trade Agreements Act of 1979, should do so (19 U.S.C. 2502). Because the effect of a standard on trade is not a criterion of section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), there is no right to a hearing on the factual question whether the revised standard would facilitate international trade, and PGAH has not sought a hearing on that issue.

Nor is a hearing warranted on the legal issue raised by PGAH's assertion that FDA may not rely on international trade consequences in promulgating food standards. The propriety of denial of a hearing on legal and policy issues is well established. (See, e.g., *Citizens for Allegan County, Inc.* v. *FPC,* 414 F. 2d 1125, 1128 (D.C. Cir. 1969); *Sun Oil Co.* v. *FPC,* 256 F. 2d 233, 240 (5th Cir.), *cert. denied,* 358 U.S. 872 (1958).) FDA regulations specifically contemplate denial of hearings on such issues (21 CFR 12.24(b)(1)).

Because an analysis of PGAH's objections and request for hearing demonstrates that PGAH has not presented sufficient grounds to justify a hearing, no hearing will be granted to PGAH.

List of Subjects in 21 CFR Part 145

Canned fruit, Food standards, Fruits.

PART 145–CANNED FRUIT

§ 145.180 [Amended]

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and regulations promulgated thereunder (21 CFR 12.22, 12.24, 12.28), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that the objections filed to the final regulation amending the standard of identity for canned pineapple under § 145.180(a)(2)(viii) and (xi) and (b)(1)(ii)(*g*) have been rejected and the request for hearing on those objections has been denied. Accordingly, the stay of this regulation, announced on March 9, 1982 (47 FR 9997), is terminated.

Effective date. Compliance with the November 24, 1981 final regulation may have begun January 25, 1982, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1985, shall fully comply.

(Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)))

Dated: December 6, 1982.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 82-33633 Filed 12-9-82; 8:45 am]

BILLING CODE 4160-01-M