§ 319.56–48 Eggplant from Israel.

Eggplant (*Solanum melongena* L.) may be imported into the continental United States from Israel only under the conditions described in this section. These conditions are designed to prevent the introduction of the following quarantine pests: *Ceratitis capitata, Eutetranychus orientalis, Helicoverpa armigera, Nipaecoccus viridis, Scirtothrips dorsalis, and Spodoptera littoralis*.

(a) *Approved pest-exclusionary structures*. The eggplant must be grown in pest-exclusionary structures in approved production sites in the Arava Valley of Israel by growers registered with the Israeli national plant protection organization (NPPO). Initial approval of the production sites must be completed jointly by the Israeli NPPO and APHIS.

(1) The pest-exclusionary structures must be equipped with double self-closing doors.

(2) Any vents or openings in the pest-exclusionary structures (other than the double self-closing doors) must be covered with 1.6 mm or smaller screening in order to prevent the entry of pests into the pest-exclusionary structure.

(3) The pest-exclusionary structures must be inspected periodically by the Israeli NPPO or its approved designee to ensure that sanitary procedures are employed to exclude plant pests and diseases and to verify that the screening is intact.

(4) The pest-exclusionary structures also must be inspected monthly for the quarantine pests listed in the introductory text of this section by the Israeli NPPO or its approved designee, beginning 2 months before harvest and continuing for the duration of the harvest. APHIS must be granted access to inspect or monitor the pest-exclusionary structures during this period as well. If, during these inspections, any quarantine pests listed in the introductory text of this section are found inside a pest-exclusionary structure, the Israeli NPPO will immediately prohibit that pest-exclusionary structure from exporting eggplant to the continental United States and notify APHIS of the action. The prohibition will remain in effect until the Israeli NPPO and APHIS agree that the risk has been mitigated.

(b) *Trapping for Medfly*. Trapping for Mediterranean fruit fly (Medfly, *Ceratitis capitata*) is required both inside and outside the pest-exclusionary structures. Trapping must begin 2 months before harvest and continue for the duration of the harvest.

(1) *Inside the pest-exclusionary structures*. APHIS-approved fruit fly traps with an approved protein bait must be placed inside the pest-exclusionary structures at a density of four traps per hectare, with a minimum of at least two traps per pest-exclusionary structure. The traps must be serviced at least once every 7 days. If a single Medfly is found in a trap inside a pest-exclusionary structure, the Israeli NPPO will immediately prohibit that pest-exclusionary structure from exporting eggplant to the continental United States and notify APHIS of the action. The prohibition will remain in effect until the Israeli NPPO and APHIS agree that the risk has been mitigated.

(2) *Outside the pest-exclusionary structures*. (i) No shade trees are permitted within 10 meters of the entry door of the pest-exclusionary structures, and no fruit fly host plants are permitted within 50 meters of the entry door of the pest-exclusionary structures. While trapping is being conducted, no fruit fly host material (such as fruit) may be brought into the pest-exclusionary structures or be discarded within 50 meters of the entry door of the pest-exclusionary structures.

(ii) A treatment jointly approved by the Israeli NPPO and APHIS must be applied for the duration of the eggplant harvest in the areas of the Arava Valley where fruit fly host material occurs in backyards.

(iii) Trapping for Medfly must be conducted by the Israeli NPPO or its approved designee throughout the year in the agricultural region along the Arava Highway 90 and in the residential area of Paran.

(iv) Trapping records must be kept and made available for APHIS review upon request.

(c) *Packinghouse procedures*. The eggplant must be packed within 24 hours of harvest in a pest-exclusionary packinghouse. While packing the eggplant for export to the continental United States, the packinghouse may only accept eggplant from approved pest-exclusionary structures. No shade trees are permitted within 10 meters of the entry door of the packinghouse, and no fruit fly host plants are permitted within 50 meters of the entry door of the packinghouse. The eggplant must be safeguarded by a pest-proof screen or plastic tarpaulin while in transit to the packinghouse and while awaiting packing. Packinghouse procedures must include culling of any visibly damaged, overripe, or infested eggplant. The eggplant must be packed in either individual insect-proof cartons or boxes labeled with the specific place of origin or non-insect-proof cartons or boxes that are covered by insect-proof mesh or plastic tarpaulins. Covered non-insect-proof cartons or boxes must be placed in shipping containers that have identification labels indicating the specific place of origin. These safeguards must remain intact until the arrival of the eggplant in the continental United States or the consignment will not be allowed to enter the continental United States.

(d) *Commercial consignments*. Eggplant from Israel may be imported in commercial consignments only.

(e) *Phytosanitary certificate*. Each consignment of eggplant must be accompanied by a phytosanitary certificate of inspection issued by the Israeli NPPO with an additional declaration reading as follows: ''The eggplant in this consignment has been grown in an approved production site and inspected and found free of the pests listed in 7 CFR 319.56*48.''

Done in Washington, DC, this 5th day of November 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–26814 Filed 11–10–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 17

[Docket No. FDA–2008–N–0561]

Maximum Civil Money Penalty Amounts and Compliance With the Federal Civil Penalties Inflation Adjustment Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing this companion proposed rule to the direct final rule, published elsewhere in this issue of the **Federal Register**, which is intended to amend our regulations to adjust for inflation the maximum civil money penalty amounts for the various civil money penalty authorities within our jurisdiction. We are taking this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (FCPIAA), as amended. The last adjustment was published in the **Federal Register** of July 20, 2004 (69 FR 43299), and the FCPIAA requires Federal agencies to adjust their civil money penalties at least once every 4 years. This proposed rule does not adjust the civil money provisions

enacted by the Food and Drug Administration Amendments Act of 2007 (FDAAA).

DATES: Submit written or electronic comments on the proposed rule by December 26, 2008. If FDA receives any timely significant adverse comments, the agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA will then proceed to respond to comments under this proposed rule using the usual notice-and-comment procedures.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2008–N–0561, by any of the following methods:
Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No. FDA–2008–N–0561 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360.

SUPPLEMENTARY INFORMATION:

I. Background

In general, the FCPIAA (28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. 3701)) requires Federal agencies to issue regulations to adjust for inflation each civil monetary penalty provided by law within their jurisdiction. The FCPIAA directs agencies to adjust the civil monetary penalties by October 23, 1996, and to make additional adjustments at least once every 4 years thereafter. The adjustments are based on changes in the cost of living, and the FCPIAA defines the cost of living adjustment as: '' * * * the percentage (if any) for each civil monetary penalty by which—(1) the Consumer Price Index for the month of June of the calendar year preceding the adjustment, exceeds (2) the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted pursuant to law'' (28 U.S.C. 2461 note, section 5(b)).

The FCPIAA also prescribes a rounding method based on the size of the penalty after the calculated increase, but states that the first adjustment of a civil monetary penalty may not exceed 10 percent of the penalty.

The FCPIAA defines a civil monetary penalty as: ''any penalty, fine, or other sanction that—(A)(i) is for a specific monetary amount as provided by Federal law; or (ii) has a maximum amount provided for by Federal law; and (B) is assessed or enforced by an agency pursuant to Federal law; and (C) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal Courts'' (28 U.S.C. 2461 note, section 3(2)).

Congress enacted the FCPIAA, in part, because it found that the impact of civil monetary penalties had been reduced by inflation and that reducing the impact of civil monetary penalties had weakened their deterrent effect.

In the **Federal Register** of July 20, 2004 (69 FR 43299), we published a final rule that identified 14 civil monetary penalties that fall within our jurisdiction and are subject to adjustments under the FCPIAA. The final rule amended our regulations governing civil money penalties hearings found at part 17 (21 CFR part 17) to establish a new § 17.2 entitled ''Maximum penalty amounts'' to show the maximum civil monetary penalty amounts that were adjusted under the FCPIAA. The final rule also revised § 17.1, which lists statutory provisions authorizing civil money penalties governed by the civil money penalty regulations as of August 28, 1995, updating the statutory citations.

II. What Changes Did We Make?

We revised the list of statutory monetary penalties in § 17.1 to include the new penalties prescribed by the Federal Food, Drug, and Cosmetic Act, as amended by FDAAA in 2007. These new penalties have been added as proposed new paragraphs (c) and (d). The table in § 17.2 has also been amended to include the new penalties, and the adjusted maximum penalty amounts for the pre-FDAAA penalties have been updated to account for the inflation between June 2004 (the year of the last adjustment) and June 2007 as prescribed by FCPIAA. The per violation amount for 21 U.S.C. 333(f)(1)(A), the per violation per person amount for 21 U.S.C. 360pp(b)(1), and the per violation amount for 42 U.S.C. 263b(h)(3) have not been adjusted because the rounding rules of FCPIAA prevent an inflation adjustment in these cases. The new FDAAA penalties have also not been adjusted because Congress only recently passed FDAAA on September 27, 2007. Finally, the ''Description of the Violation'' column in the table in § 17.2 is proposed to be removed, as it is unnecessary for purposes of merely showing the adjustment in penalty amounts.

III. What is Proposed?

In brief, the proposed rule would:

- Revise § 17.1 to update the statutory citations regarding the new civil monetary penalties prescribed by FDAAA, and
- Revise the table in § 17.2 to include the new FDAAA penalties, and adjusts the pre-FDAAA maximum civil penalty amounts for inflation as prescribed by FCPIAA.

IV. Additional Information

This proposed rule incorporates requirements specifically set forth in the FCPIAA requiring FDA to issue a

regulation implementing inflation adjustments for all its civil penalty provisions. These technical changes, required by law, do not substantively alter the existing regulatory framework, nor do they in any way affect the terms under which civil penalties are assessed by FDA. The formula for the amount of the penalty adjustment is prescribed by Congress in the FCPIAA, and these changes are not subject to the exercise of discretion by FDA. In addition, FDA has made conforming changes to the regulations, which have no substantive effect, to reflect the new penalties prescribed by Congress in FDAAA.

This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. This companion proposed rule and the direct final rule are identical in substance. This companion proposed rule will provide the procedural framework to proceed with standard notice-and-comment rulemaking in the event the direct final rule receives significant adverse comment and is withdrawn. The comment period for the companion proposed rule runs concurrently with the comment period of the direct final rule. Any comments received under the companion proposed rule will be treated as comments regarding the direct final rule and vice versa.

A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment states why this rule would be ineffective without the additional change.

If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to the companion proposed rule. Instead, we will publish a confirmation document within 30 days after the comment period ends. We intend the direct final rule to become effective 30 days after publication of the confirmation document.

If we receive significant adverse comments, we will withdraw the direct final rule. We will proceed to respond to all the comments received regarding the direct final rule, treating those comments as comments to this proposed rule. The agency will address the comments in the subsequent final rule. We will not provide additional opportunity for comment. If we receive a significant adverse comment which applies to part of the rule and that part may be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of significant adverse comment.

For additional background information, see the corresponding direct final rule published elsewhere in this issue of the **Federal Register**.

V. Environmental Impact

We have determined under 21 CFR 25.30(a) and (h) 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.

VI. Paperwork Reduction Act 1995

We conclude that the civil monetary penalties adjustments in this proposed rule are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The adjustments do not require disclosure of any information to FDA, third parties, or the public.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule simply proposes to adjust the maximum amount of civil monetary penalties administered by FDA, and because the adjustment is required by the FCPIAA, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $130 million, using the most current (2007) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

IX. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. This comment period runs concurrently with the comment period for the direct final rule; any comments received will be considered as comments regarding the direct final rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

List of Subjects in 21 CFR Part 17

Administrative practice and procedure, Penalties.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 17 is amended as follows:

PART 17—CIVIL MONEY PENALTIES HEARINGS

1. The authority citation for 21 CFR part 17 continues to read as follows:

Authority: 21 U.S.C. 331, 333, 337, 351, 352, 355, 360, 360c, 360f, 360i, 360j, 371; 42 U.S.C. 262, 263b, 300aa–28; 5 U.S.C. 554, 555, 556, 557.

2. Section 17.1 is amended by redesignating paragraphs (c) through (g) as paragraphs (e) through (i) and by adding new paragraphs (c) and (d) to read as follows:

§ 17.1 Scope.

* * * * *

(c) Section 303(f)(3) of the act authorizing civil money penalties for certain violations relating to the submission of certifications and/or clinical trial information to the clinical trial data bank and section 303(f)(4) of the act authorizing civil money penalties for certain violations of the act relating to postmarket studies, clinical trial requirements, and risk evaluation and mitigation strategies for drugs.

(d) Section 303(g)(1) of the act authorizing civil money penalties for certain violations of the act that relate to dissemination of direct-to-consumer advertisements for approved drugs or biological products.

* * * * *

3. Section 17.2 is revised to read as follows:

§ 17.2 Maximum penalty amounts.

The following table shows maximum civil monetary penalties associated with the statutory provisions authorizing civil monetary penalties under the act or the Public Health Service Act.

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
21 U.S.C.				
333(b)(2)(A)	55,000	For each of the first two violations in any 10-year period	2008	60,000
333(b)(2)(B)	1,100,000	For each violation after the second conviction in any 10-year period	2008	1,200,000
333(b)(3)	110,000	Per violation	2008	120,000
333(f)(1)(A)	16,500	Per violation	2008	16,500 (not adjusted)
333(f)(1)(A)	1,100,000	For the aggregate of violations	2008	1,200,000
333(f)(2)(A)	55,000	Per individual	2008	60,000
333(f)(2)(A)	275,000	Per ''any other person''	2008	300,000
333(f)(2)(A)	550,000	For all violations adjudicated in a single proceeding	2008	600,000
333(f)(3)(A)	10,000	For all violations adjudicated in a single proceeding	2007	10,000 (not adjusted)
333(f)(3)(B)	10,000	For each day the violation is not corrected after a 30-day period following notification until the violation is corrected	2007	10,000 (not adjusted)
333(f)(4)(A)(i)	250,000	Per violation	2007	250,000 (not adjusted)
333(f)(4)(A)(i)	1,000,000	For all violations adjudicated in a single proceeding	2007	1,000,000 (not adjusted)
333(f)(4)(A)(ii)	250,000	For the first 30-day period (or any portion thereof) of continued violation following notification	2007	250,000 (not adjusted)
333(f)(4)(A)(ii)	1,000,000	For any 30-day period, where the amount doubles for every 30-day period of continued violation after the first 30-day period	2007	1,000,000 (not adjusted)
333(f)(4)(A)(ii)	10,000,000	For all violations adjudicated in a single proceeding	2007	10,000,000 (not adjusted)

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—Continued

U.S.C. Section	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty Figure or Adjustment	Adjusted Maximum Penalty Amount (in dollars)
333(g)(1)	250,000	For the first violation in any 3-year period	2007	250,000 (not adjusted)
333(g)(1)	500,000	For each subsequent violation in any 3-year period	2007	500,000 (not adjusted)
335b(a)	275,000	Per violation for an individual	2008	300,000
335b(a)	1,100,000	Per violation for ''any other person''	2008	1,200,000
360pp(b)(1)	1,100	Per violation per person	2008	1,100 (not adjusted)
360pp(b)(1)	330,000	For any related series of violations	2008	355,000
42 U.S.C.				
263b(h)(3)	11,000	Per violation	2008	11,000 (not adjusted)
300aa–28(b)(1)	110,000	Per occurrence	2008	120,000

Dated: October 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–26864 Filed 11–10–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–222P]

RIN 1117–AA64

Exempt Chemical Mixtures Containing Gamma-Butyrolactone

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: DEA is proposing that chemical mixtures that are 70 percent or less gamma-butyrolactone (GBL), by weight or volume, be automatically exempt from regulatory controls under the Controlled Substances Act (CSA). DEA is seeking through this rulemaking to exempt only those chemical mixtures that do not represent a significant risk of diversion. If finalized as proposed, this regulation would result in GBL chemical mixtures, in concentrations greater than 70 percent, becoming subject to List I chemical regulatory requirements of the CSA, except if exempted through an existing categorical exemption. DEA is taking this action because there is a serious threat to the public safety associated with the ease by which GBL is chemically converted to the schedule I controlled substance gamma-hydroxybutyric acid (GHB).

DEA recognizes that concentration criteria alone cannot identify all mixtures that warrant exemption. As a result, 21 CFR 1310.13 provides for an application process by which manufacturers may obtain exemptions from CSA regulatory controls for those GBL chemical mixtures that are not automatically exempt under the concentration criteria.

DATES: Written comments must be postmarked and electronic comments sent on or before January 12, 2009.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–222p'' on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to Drug Enforcement Administration, *Attention:* DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your