order regulating the handling of milk in the Iowa marketing area is being considered for September 1, 1998, through November 30, 1998.

All persons who desire to submit written data, views or arguments about the proposed revision should send two copies of their views to USDA/AMS/Dairy Programs, Order Formulation Branch, Room 2971, South Building, P.O. Box 96456, Washington, DC 20090–6456 by the 30th day after publication of this notice in the **Federal Register**. The filing period is limited to 30 days because a longer period would not provide the time needed to complete the required procedures and include September in the temporary revision period.

All written submissions made pursuant to this notice will be made available for public inspection in the Dairy Programs offices during regular business hours (7 CFR 1.27(b)).

Statement of Consideration

The provision proposed to be revised is the percentage of a supply plant's receipts required to be shipped to pool distributing plants pursuant to § 1079.7(b) of the Iowa Federal milk marketing order (Order 79). As proposed, the percentage of a supply plant's receipts that must be shipped to pool distributing plants (fluid milk plants) if the supply plant is to be considered a pool plant would be decreased by the maximum allowable 10 percentage points, from 35 percent to 25 percent for the period September 1, 1998, through November 30, 1998.

Section 1079.7(b)(1) of the Iowa milk marketing order allows the Deputy Administrator, Dairy Programs, to reduce or increase a pool supply plant's minimum shipping requirement by up to 10 percentage points to prevent uneconomic milk shipments or to assure an adequate supply of milk for fluid use.

Beatrice Cheese, Inc. (Beatrice), a proprietary manufacturer of dairy products in Fredericksburg, Iowa, is regulated under Order 79 as a pool supply plant. Beatrice requested that the shipping percentage be reduced by 10 percentage points for the months of September through November 1998. The handler's request states that this decrease is warranted due to the fact that current raw milk supplies available for fluid use exceed the needs of the fluid milk plants in Order 79. Beatrice states that if the pool supply shipping percentages remain unchanged, Beatrice will be forced to move milk uneconomically or unfairly depool some milk produced by Iowa dairymen, denying them participation in the Order 79 pool.

In view of the current supply and demand relationship, it may be necessary to decrease the shipping percentage requirements for pool supply plants to provide for the efficient and economic marketing of milk during the period September 1, 1998, through November 30, 1998.

List of Subjects in 7 CFR Part 1079

Milk marketing orders.

The authority citation for 7 CFR part 1079 continues to read as follows:

Authority: 7 U.S.C. 601–674.

Dated: July 21, 1998.

Richard M. McKee,

Deputy Administrator, Dairy Programs.

[FR Doc. 98–19908 Filed 7–24–98; 8:45 am]

BILLING CODE 3410–02–P

NORTHEAST DAIRY COMPACT COMMISSION

7 CFR Part 1301

Notice of Meeting

AGENCY: Northeast Dairy Compact Commission.

ACTION: Notice of Meeting.

SUMMARY: The Compact Commission will hold its monthly meeting to consider whether to adopt as a Final rule the Proposed Rule to amend the current Compact Over-order Price Regulation to exclude milk from the pool which is either diverted or transferred, in bulk, out of the Compact regulated area. The Commission will also consider whether to adopt as a Final Rule the Proposed Rule to establish a reserve fund for reimbursement to school food authorities. Matters relating to administration and the price regulation to include the reports and recommendations of the Commission's standing Committees and action upon the Proposed Amendments to the Bylaws as noticed to the Commission at the July 1, 1998 are also scheduled.

DATES: The meeting is scheduled for Wednesday, August 5, 1998 to commence at 10:00 a.m.

ADDRESSES: The meeting will be held at the Holiday Inn, Capitol Room, 172 North Main Street, Concord, NH (exit 14 off I–93).

FOR FURTHER INFORMATION CONTACT: Kenneth Becker, Executive Director, Northeast Dairy Compact Commission, 43 State Street, PO Box 1058, Montpelier, VT 05601. Telephone (802) 229–1941.

SUPPLEMENTARY INFORMATION: The Compact Commission will hold its monthly meeting to consider whether to adopt as a Final rule the Proposed Rule to amend the current Compact Over-order Price Regulation to exclude milk from the pool which is either diverted or transferred, in bulk, out of the Compact regulated area. The proposal will limit the payment of the compact over-order producer price to milk disposed of within the Compact regulated area. The Commission will also consider whether to adopt as a Final Rule the Proposed Rule to establish a reserve fund for reimbursement to school food authorities. The current Compact Over-order Price Regulation is codified at 7 CFR 1300 through 1308. The proposed reserve fund is required to implement the previously issued regulation exempting certain milk sold by school food authorities from the Over-order Price Regulation. Matters relating to administration and the price regulation to include the reports and recommendations of the Commission's standing Committees and action upon the Proposed Amendments to the Bylaws as noticed to the Commission at the July 1, 1998, as required, are also scheduled.

(Authority: (a) Article V, Section 11 of the Northeast Interstate Dairy Compact, and 7 U.S.C. 7256.)

Kenneth Becker,

Executive Director.

[FR Doc. 98–19923 Filed 7–24–98; 8:45 am]

BILLING CODE 1650–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 20

[Docket No. 98N–0518]

Public Information; Communications With State and Foreign Government Officials

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing communications with State and foreign government officials. The proposed rule would permit FDA to disclose confidential commercial information to international organizations having responsibility to facilitate global or regional harmonization of standards and requirements. These disclosures would, in almost all instances, occur only with

the consent of the person providing the confidential commercial information to FDA. The proposed rule would also streamline the process for FDA officials to disclose certain nonpublic, predecisional documents (such as draft rules and guidance documents) to State and foreign government officials. The proposal does not alter current procedures for sharing documents that contain confidential commercial information. These changes are intended to facilitate information exchanges with State and foreign governments and certain international organizations.

DATES: Written comments by October 13, 1998.

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

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of December 24, 1974 (39 FR 44602), FDA published a regulation implementing the Freedom of Information Act and other laws that affect public access to government records and information. The rule exempted certain records, such as law enforcement records, from public disclosure, but did not include any provisions for special disclosures to foreign government officials of documents that were not available to the public generally.

In the **Federal Register** of November 19, 1993 (58 FR 61598), FDA published a final rule which, among other things, authorized the agency to disclose confidential commercial information concerning FDA-regulated products to foreign government officials who perform counterpart functions to FDA. The rule, which is now codified at § 20.89 (21 CFR 20.89), permits these disclosures to occur only under various safeguards, such as a written statement from the foreign government agency establishing its authority to protect the confidential commercial information from public disclosure and a written commitment not to disclose such information without the consent of the sponsor for the confidential commercial information or written confirmation from FDA that the information is no longer confidential. Additionally, the rule requires FDA to determine either that the sponsor of the confidential commercial information has authorized the disclosure to the foreign government, or that disclosure would be in the interest of public health, or that disclosure is to a foreign scientist visiting FDA as part of a joint review or long-term cooperative training effort and subject to other restrictions. FDA included these safeguards to protect sensitive commercial information and to lessen industry concerns that foreign governments would further disclose such information without the sponsor's permission.

Later, in the **Federal Register** of December 8, 1995 (60 FR 63372), FDA issued a final rule to permit FDA to disclose nonpublic, predecisional and other documents, such as draft guidance documents and regulations, to State and foreign government officials. (Currently, the term ''nonpublic, predecisional document,'' as used in §§ 20.88(e) (21 CFR 20.88) and 20.89(d), does not include documents containing confidential commercial information such as FDA-prepared documents that analyze confidential commercial information.) Disclosures of nonpublic, predecisional documents were subject to certain safeguards similar to those in the 1993 rule (58 FR 61598), such as a written statement by the State or foreign government agency establishing its authority to protect the nonpublic, predecisional documents from public disclosure and a commitment not to disclose such documents without FDA's written confirmation that the documents no longer have nonpublic status (see §§ 20.88(e)(1)(i) and 20.89(d)(1)(i)).

The 1995 final rule (60 FR 63372) also stated that, for purposes of disclosing nonpublic, predecisional documents, the term ''official of a foreign government agency'' includes, but is not limited to, ''an agent contracted by the foreign government, and an employee of an international organization having responsibility to facilitate global harmonization of standards and requirements in FDA's areas of responsibility'' (see 21 CFR 20.89(d)(3)). This enabled FDA to disclose nonpublic, predecisional documents to international organizations such as the World Health Organization and the Food and Agriculture Organization of the United Nations.

The 1995 rule also established similar authority for disclosing both confidential commercial information and nonpublic, predecisional documents to U.S. State government officials.

FDA's experience under § 20.89 has been excellent. Thus far, disclosures of confidential commercial information to foreign governments have occurred with the sponsor's consent in almost every case, and only after the foreign government has provided the necessary documents establishing its authority to protect the shared confidential commercial information from disclosure. These documents are usually written commitments that the foreign government has the authority to protect the documents from public disclosure and will protect such documents provided by FDA, although, on occasion, the document may be an exchange of letters or other agreement between FDA and the foreign country (see, e.g., 62 FR 60901, November 13, 1997) (exchange of letters between FDA and the Australian Therapeutic Goods Administration regarding information about a drug or biologic being considered for orphan status)).

A sponsor's consent is not always necessary under § 20.89. FDA may disclose confidential commercial information without the sponsor's consent where the agency determines that disclosure would be in the interest of public health by reason of the foreign government's possession of information concerning a product's safety, efficacy, or quality or information concerning an investigation.

Generally, the confidential information which FDA has shared has consisted of internal FDA documents discussing data (rather than the data themselves) as the foreign governments usually have the data in an application for marketing authorization.

Disclosures of nonpublic, predecisional information, mostly involving draft guidance documents, have been less frequent, and all have involved disclosures to foreign governments.

As for disclosures to international organizations, current FDA regulations expressly permit the agency to disclose nonpublic, predecisional documents, but do not permit disclosures of confidential commercial information, including FDA-prepared documents that discuss confidential commercial information, to international organizations.

II. Description of the Proposed Rule

FDA is now contemplating possible arrangements with international organizations in which FDA may want to be able to disclose confidential commercial information to international organizations under the same conditions and procedures found in § 20.89 for disclosing confidential commercial information to foreign governments. The agency is not proposing to change those conditions or procedures with respect to sharing confidential commercial

information with foreign governments. The proposal would simply add international organizations to the disclosure provisions of § 20.89 dealing with confidential commercial information.

For example, an international organization may wish to request certain confidential commercial information from FDA so that it may investigate possible adverse events associated with an approved drug product or as part of a cooperative investigation. This occurred recently when the Pan American Health Organization (PAHO) sought certain product and manufacturing information from FDA after an incident in Haiti where over 80 children died and even more were injured by an acetaminophen syrup contaminated with diethylene glycol. FDA was able to share the information with PAHO only after information had been publicly disclosed by non-FDA sources. As stated earlier, current FDA regulations do not explicitly provide a mechanism for providing confidential commercial information to an international organization even under the same circumstances in which FDA can provide confidential commercial information to a foreign government under § 20.89.

The proposal would amend § 20.89 to clarify that disclosures of confidential commercial information and nonpublic, predecisional documents may be made to an international organization having responsibility to facilitate harmonization of standards and requirements in FDA's areas of responsibility. Thus, the proposed rule would move the language regarding an ''official of a foreign government agency'' from § 20.89(d)(3), where it applies only to disclosures of nonpublic, predecisional documents, to a new § 20.89(e) so that it would apply to all disclosures under § 20.89. The proposal would also revise the reference to international organizations to refer to international organizations that facilitate ''global or regional'' harmonization of standards and requirements. The reference to ''regional'' harmonization efforts is intended to reflect the fact that some international organizations operate primarily on a regional, rather than global, scale. (FDA, for purposes of this rule, interprets the term ''international organizations'' as referring to public or intergovernmental organizations, whether established by treaties or other means, instead of private or nongovernmental organizations.)

The proposal would also clarify that the term ''official of a foreign government'' includes both temporary and permanent employees and agents. When FDA first proposed § 20.89(d)(3) on January 27, 1995 (60 FR 5530), the term ''official of a foreign government'' was understood as including foreign government employees. Comments submitted in response to the 1995 proposed rule (60 FR 5530) suggested including ''agents'' of a foreign government, and so FDA amended the rule to include ''agents'' on December 8, 1995 (60 FR 63372 at 63377). However, the express mention of agents, and not employees of a foreign government, has caused some confusion, and so FDA is proposing to amend the rule to refer to employees of and agents contracted by a foreign government or by an international organization. This change would be especially appropriate for international organizations because many international organizations rely on government officials who are temporarily assigned to the international organization and on consultants and contractors. It would also be analogous to the existing requirements for FDA's consultants, advisory committee members, and commissioned officials who are subject to the same disclosure restrictions that apply to FDA employees even though such persons are not agency employees themselves (see 21 CFR 20.84).

Additionally, the proposed rule would amend §§ 20.88(e)(1)(i) and 20.89(d)(1)(i) to eliminate the need for the written statement from a U.S. State or a foreign government agency official when FDA provides nonpublic, predecisional documents. The requirement of a written statement was originally included to mirror the existing parallel requirement for such a statement before FDA disclosed any confidential commercial information to a foreign government. However, because information exchanges involving nonpublic, predecisional documents do not contain confidential commercial information, the written statement adds little value because only FDA's deliberative interests would be directly affected by a premature public disclosure. Furthermore, FDA's experience under § 20.89 suggests that the written statement requirement is contrary to customary international practice in which drafts are shared with trusted individuals in counterpart agencies as part of a well-understood, well-established practice that the document will not be disclosed or made public. Moreover, some foreign agencies have been reluctant to execute the written statement due to uncertainties as to who in their government possesses the authority to sign such a statement. Others have even expressed concern that the written statement might, under their government's policies or laws, be considered an international agreement under international treaty law that might require new national legislation or legislative consent.

Thus, the proposed rule would delete the written statement from § 20.89(d) for exchanges involving nonpublic, predecisional information. Furthermore, the proposal would delete the written statement from § 20.88(e) so that State government officials have the same access to nonpublic, predecisional documents as foreign government officials. The agency will require State and foreign governments to execute a written statement establishing their authority to protect documents from public disclosure only where the documents contain confidential commercial information.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(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.

IV. Analysis of Impacts

FDA has examined the impacts of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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 new benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and the principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined in 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. The proposed rule will have no significant economic impact on small entities under the Regulatory Flexibility Act because it regulates only conduct of FDA, foreign governments, and international organizations, and not small entities under the Regulatory Flexibility Act. In any case, the proposed rule will have no significant economic impact on any small entities.

The proposed rule would authorize FDA to disclose confidential commercial information to international organizations, subject to the same safeguards against public disclosure of that information that apply in the case of disclosures to foreign government agencies and to disclose predecisional information to foreign governments under relaxed procedures. These disclosures would likely facilitate marketing review and approval of various FDA-regulated products in foreign countries, and disclosures would almost always occur only with the consent of the business that generated the confidential commercial information. This beneficial effect of the rule would outweigh any possible adverse impact. Thus, the agency certifies that this proposed rule will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required. FDA requests comment on this conclusion.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Interested persons may, on or before October 13, 1998, 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 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 20 be amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 is revised to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

2. Section 20.88 is amended by revising paragraph (e)(1)(i) to read as follows:

§ 20.88 Communications with State and local government officials.

* * * * *

(e)(1) * * *

(i) The State government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

* * * * *

3. Section 20.89 is amended by revising paragraph (d)(1)(i), by removing paragraph (d)(3), and by adding paragraph (e) to read as follows:

§ 20.89 Communications with foreign government officials.

* * * * *

(d)(1) * * *

(i) The foreign government agency has the authority to protect such nonpublic documents from public disclosure and will not disclose any such documents provided without the written confirmation by the Food and Drug Administration that the documents no longer have nonpublic status; and

* * * * *

(e) For purposes of this section, the term ''official of a foreign government agency'' includes, but is not limited to, employees (whether temporary or permanent) of and agents contracted by the foreign government or by an international organization having responsibility to facilitate global or regional harmonization of standards and requirements in the Food and Drug Administration's areas of responsibility. For such officials, the statement and commitment required by paragraph (d)(1)(i) of this section shall be provided by both the organization and the individual.

Dated: July 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–19898 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 120

[Docket Nos. 97N–0511, 93N–0325, and 97N–0296]

RIN 0910–AA43

Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice; Extension of Comment Period; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; preliminary regulatory impact analysis; extension of comment period; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of July 8, 1998 (63 FR 37057). The document extended the comment period on a proposed rule published in the **Federal Register** of April 24, 1998, to ensure the safe and sanitary processing of fruit and vegetable juices and juice products and on the related preliminary regulatory impact analysis and initial regulatory flexibility analysis published in the **Federal Register** of May 1, 1998. The document was published with an incorrect agency contact. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4681.

SUPPLEMENTARY INFORMATION: In FR Doc. 98–18286, appearing on page 37057 in the **Federal Register** of Wednesday, July 8, 1998, the following correction is made:

1. On page 37057, in the second column, the agency contact is corrected to read ''**FOR FURTHER INFORMATION CONTACT:** Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4681.''

Dated: July 17, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–19954 Filed 7–24–98; 8:45 am]

BILLING CODE 4160–01–F