to provide evidence, including opinions, on the nature and severity of your impairment(s). Although we consider opinions from medical sources on issues such as whether your impairment(s) meets or equals the requirements of any impairment(s) in the Listing of Impairments in appendix 1 to subpart P of part 404 of this chapter, your residual functional capacity (see §§ 416.945 and 416.946), or the application of vocational factors, the final responsibility for deciding these issues is reserved to the Commissioner.

(3) We will not give any special significance to the source of an opinion on issues reserved to the Commissioner described in paragraphs (e)(1) and (e)(2) of this section.

(f) *Opinions of nonexamining sources.* We consider all evidence from nonexamining sources to be opinion evidence. When we consider the opinions of nonexamining sources, we apply the rules in paragraphs (a) through (e) of this section. In addition, the following rules apply to State agency medical and psychological consultants, other program physicians and psychologists, and medical experts we consult in connection with administrative law judge hearings and Appeals Council review:

* * * * *

(2) Administrative law judges are responsible for reviewing the evidence and making findings of fact and conclusions of law. They will consider opinions of State agency medical or psychological consultants, other program physicians and psychologists, and medical experts as follows:

(i) Administrative law judges are not bound by any findings made by State agency medical or psychological consultants, or other program physicians or psychologists. However, State agency medical and psychological consultants and other program physicians and psychologists are highly qualified physicians and psychologists who are also experts in Social Security disability evaluation. Therefore, administrative law judges must consider findings of State agency medical and psychological consultants or other program physicians or psychologists as opinion evidence, except for the ultimate determination about whether you are disabled. See § 416.912(b)(6).

(ii) When an administrative law judge considers findings of a State agency medical or psychological consultant or other program physician or psychologist, the administrative law judge will evaluate the findings using relevant factors in paragraphs (a) through (e) of this section, such as the physician's or psychologist's medical specialty and expertise in our rules, the supporting evidence in the case record, supporting explanations provided by the physician or psychologist, and any other factors relevant to the weighing of the opinions. Unless the treating source's opinion is given controlling weight, the administrative law judge must explain in the decision the weight given to the opinions of a State agency medical or psychological consultant or other program physician or psychologist, as the administrative law judge must do for any opinions from treating sources, nontreating sources, and other nonexamining sources who do not work for us.

(iii) Administrative law judges may also ask for and consider opinions from medical experts on the nature and severity of your impairment(s) and on whether your impairment(s) equals the requirements of any impairment listed in appendix 1 to subpart P of part 404 of this chapter. When administrative law judges consider these opinions, they will evaluate them using the rules in paragraphs (a) through (e) of this section.

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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: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing final regulations governing communications with State and foreign government officials. The rule states that FDA may disclose confidential commercial information to international organizations having responsibility to facilitate global or regional harmonization of standards and requirements. These disclosures will, in almost all instances, occur only with the consent of the person who submitted the confidential commercial information to FDA. The rule also streamlines 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 rule 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: This rule becomes effective on May 22, 2000.

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

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of July 27, 1998 (63 FR 40069), FDA published a proposed rule that would facilitate its communications with foreign governments. Current FDA regulations at § 20.89 (21 CFR 20.89) permit FDA to disclose confidential commercial information and nonpublic, predecisional documents to foreign governments. Nonpublic, predecisional documents are disclosed under § 20.89(d) only if they do not contain unredacted confidential commercial information (such as draft FDA guidance documents or regulations). These disclosures are subject to certain safeguards. These safeguards include obtaining a written statement from the foreign government agency establishing that agency's authority to protect the confidential commercial information from public disclosure, and a written commitment not to disclose such information without written permission from the person who created or submitted the confidential commercial information (the ''sponsor'') or written confirmation from FDA that the information is no longer confidential. Similar safeguards exist regarding exchanges of nonpublic, predecisional information.

A similar regulation for communications with State government officials exists at § 20.88 (21 CFR 20.88).

FDA published the proposed rule to accomplish several goals. First, the proposed rule would amend §§ 20.88(e)(1)(i) and 20.89(d)(1)(i) to eliminate the requirement for the written statement and written commitment for exchanges involving solely nonpublic, predecisional information. As explained in the preamble to the proposed rule, it appears that requiring written

statements from the receiving foreign government agencies is contrary to customary international practice, in which drafts of such documents are routinely shared with trusted individuals in foreign government counterpart agencies as part of a well—understood and well—established practice that provides that those individuals and their agencies will not disclose the documents or make them public (63 FR 40069 at 40071). FDA's experience with § 20.89 also indicates that officials in some foreign agencies have been reluctant to execute these written statements for various reasons, including uncertainty as to who in their respective government agencies possesses the requisite authority to sign such a statement, or concerns that the written statements might, under their government's policies or laws, be considered an international agreement that might require new national legislation or legislative consent. FDA further noted in the preamble to the proposed rule that, because the information exchanges in question involve nonpublic, predecisional documents that do not contain confidential commercial information, the written statements add little value to protecting the information exchange process because only FDA's deliberative interests would be directly affected by a premature public disclosure.

Second, the proposal would revise § 20.89 to permit FDA to disclose to international organizations both confidential commercial information and nonpublic, predecisional information. Disclosures of confidential commercial information to an international organization would be subject to the same safeguards that apply to disclosures of such information to foreign government agencies, including a written statement, a written commitment, and, in most cases, the sponsor's consent. The preamble to the proposed rule described an instance in which the Pan American Health Organization (PAHO) requested certain manufacturing and product quality information from FDA after a product contamination incident, and FDA was unable to disclose the information to PAHO until non-FDA sources had publicly disclosed the information (63 FR 40069 at 40071). Thus, the proposal would address situations in which an international organization seeks to obtain confidential commercial information from FDA by moving 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 would reflect the fact that some international organizations operate primarily on a regional, rather than global, scale.

Finally, the proposed rule would clarify that the term ''official of a foreign government'' in proposed § 20.89(e) includes, but is not limited to, permanent and temporary employees of, and agents contracted by, a foreign government. This clarification was needed because the existing rule expressly mentioned agents, but not employees of the foreign government (63 FR 40069 at 40071).

II. Discussion of Comments on the Proposed Rule

FDA received four comments on the proposed rule, including one comment from a foreign government. Three comments, submitted by pharmaceutical companies and a trade association, opposed the rule. The fourth comment, submitted by a foreign government agency, supported the rule.

A. Sections 20.88(e)(1) and 20.89(d)(1)—Eliminating the Requirement of a Written Statement and a Written Commitment From State and Foreign Governments for Exchanges of Nonpublic, Predecisional Documents

As stated earlier, the proposal would revise §§ 20.88(e)(1) and 20.89(d)(1) to eliminate the requirement whereby a U.S. State or foreign government agency official must provide a written statement concerning that agency's ability to protect nonpublic, predecisional documents from public disclosure and a written commitment not to disclose any nonpublic, predecisional documents without FDA's written confirmation that the document no longer has nonpublic status.

1. One comment from a foreign government agency stated that it ''welcome[s] FDA's recognition that the previous requirement for a written undertaking has been contrary to customary international practice'' and that it, too, was aware that ''in some countries legal difficulties have arisen over providing FDA with such undertakings.'' The comment stated that the rule would help simplify communications between the two countries.

In contrast, one comment from a pharmaceutical trade association opposed giving nonpublic, predecisional documents to State and foreign governments, stating that FDA's rationale was ''difficult to follow,'' that the written statements are not ''overly burdensome,'' and that FDA would be ''putting the competitive interests of United States companies at risk.'' The comment added that ''the concerns expressed by foreign governments are not applicable to United States government agencies'' and that ''the exemptions from [the Freedom of Information Act] for pre-decisional documents and confidential commercial information should not be undermined by allowing this information to be available at the state level by virtue of differing state laws.''

The final rule eliminates the need for a written statement and a written commitment from State and foreign government agencies when exchanges of nonpublic, predecisional documents are involved. FDA reiterates that these are documents that FDA creates; examples include draft regulations and draft guidance documents. Nonpublic, predecisional documents prepared by FDA normally do not contain confidential commercial information. If FDA prepared a document that contained confidential commercial information, that material would be considered, for purposes of §§ 20.88 and 20.89, to be confidential commercial information, rather than a nonpublic, predecisional document. Therefore, the provisions of §§ 20.88 and 20.89 pertaining to confidential commercial information would apply. Alternatively, FDA could redact the confidential commercial information before providing the nonpublic, predecisional document to the State or foreign government agency. Because the nonpublic, predecisional documents that FDA would provide to State and foreign governments would not contain confidential commercial information, their exchange would not place U.S. companies at a competitive disadvantage internationally or domestically.

The written statement and written commitment requirement for nonpublic, predecisional documents that published in the **Federal Register** of December 8, 1995 (60 FR 63372) (hereinafter referred to as the 1995 final rule), was more formal than customary international practice and presented legal or legislative challenges to some foreign governments. The comment from the foreign government clearly and unequivocally supports FDA's rationale. While the comment opposing the proposal states that U.S. government agencies do not have to remedy issues

or problems faced by a foreign government, FDA cannot ignore the fact that the written statement and written commitment requirement departed from customary international practice and impeded the very exchange of information that the 1995 final rule was intended to promote.

To illustrate the problem, FDA has received requests for draft documents from certain foreign government officials in order to harmonize international regulatory efforts on a particular subject. The written statement and written commitment requirement, on occasion, has presented an obstacle to the information exchange because the foreign government agency was uncertain as to whether such a statement, under the foreign country's law, would be considered to be a treaty or international agreement or because the foreign government agency was uncertain as to which official had the authority to sign a written statement and written commitment of this sort and provide it to another country. These uncertainties frustrated the intent behind § 20.89 because, without the written statement and written commitment from the foreign government, FDA could not provide the draft to the foreign government, and the opportunity for international collaboration on the draft was lost. Thus, contrary to the opposing comment's belief, a foreign government's ''problems'' with the written statement and written commitment requirement can affect FDA as well as the foreign government agency.

FDA also does not accept the suggestion that nonpublic, predecisional information should not be available to State governments. FDA's regulations have provided for exchanges of nonpublic, predecisional information with certain State officials (those who have been commissioned under section 702 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372) and those under contract with FDA) and with State governments since the 1995 final rule, and the 1998 proposal did not contain any amendments or revisions (aside from the removal of the written statement and written commitment requirement) that would affect the availability of nonpublic, predecisional information to State government agencies. FDA further notes that it would be an odd result if FDA could provide nonpublic, predecisional information to a foreign government, but could not provide the same information to a State government in the United States. Similarly, it would be an odd result if FDA required State government agencies to provide greater assurance, compared to foreign governments, that they would protect nonpublic, predecisional documents from disclosure, especially when, in both cases, it is only governmental interests, not individual companies' interests, that would be adversely affected by an unauthorized disclosure.

B. Section 20.89(e)—Amending the Term ''Official of a Foreign Government Agency''

1. The Inclusion of Temporary and Permanent Employees and Agents

As stated earlier, proposed § 20.89(e) would clarify that the term ''official of a foreign government'' includes both temporary and permanent foreign government employees and agents. FDA proposed this change because the existing language, at § 20.89(d)(3), expressly mentions agents, but not employees, of a foreign government. The proposal also would construe the term ''official of a foreign government'' as including temporary as well as permanent employees and agents. The inclusion of temporary employees and agents is meant to cover those situations where a foreign government employee is temporarily assigned to an international organization.

2. One comment noted that the proposal did not expressly state whether foreign consultants are subject to any restrictions on the disclosure of information that FDA provides to a foreign government or to an international organization. The comment further noted that proposed § 20.89(e) would require written statements from an international organization and individuals in the international organization, but that proposed § 20.89(d)(1)(i) would eliminate the written statements.

The reference to employees and agents in proposed § 20.89(e) was not intended to exclude consultants to a foreign government agency. FDA considers consultants to be ''agents'' within proposed § 20.89(e) and expects that such persons will adhere to the foreign government's written statement and written commitment regarding confidential commercial information and adhere to the foreign government agency's customary practice of not disclosing nonpublic, predecisional information supplied by a different government. In the event of an unauthorized disclosure, FDA will hold both the responsible individual and the foreign government agency accountable, and will take appropriate action.

As for the comment's statement that proposed §§ 20.89(d)(1)(i) and 20.89(e) conflict on the need for a written statement and written commitment, FDA agrees and has modified § 20.89(e) to clarify that written statements and written commitments are required on behalf of both the international organization and the individual involved when confidential commercial information is being disclosed.

2. Providing Confidential Commercial Information to International Organizations

Several comments strongly opposed the language in proposed § 20.89(e) which would enable FDA to provide confidential commercial information to international organizations.

3. Three comments challenged the agency's basis for the proposal. Two comments argued that an international organization such as PAHO has no role in matters that would require it to receive confidential commercial information, has no enforcement authority, and might not even be considered to have a role in harmonizing standards or requirements. Alternatively, one comment stated that, even if an international organization is responsible for global or regional harmonization of standards, it is unclear why such international organizations need confidential commercial information, especially in situations where there is no public health concern.

The preamble to the proposed rule described an incident in Haiti where PAHO assisted Haiti's Ministry of Health in investigating a kidney failure epidemic in which nearly 90 children died. The problems were traced to a contaminated liquid acetaminophen product manufactured in Haiti, and FDA assisted the Haitian government by examining the pharmaceutical company, obtaining samples, and conducting laboratory tests. FDA prepared an inspection report that contained some confidential commercial information. Consequently, when PAHO requested the report, FDA was unable to provide the information because the existing FDA regulation did not provide for disclosing confidential commercial information to an international organization. FDA provided the information to PAHO only after FDA learned that non-FDA sources had publicly disclosed the information.

This example illustrates that an international organization may, indeed, have a need for confidential commercial information from FDA. FDA also disagrees with the comment that suggested that no public health concerns existed in the PAHO example because, at the time of the investigation, the number of children who had died or

had become ill due to the contaminated product was rising, and officials were not certain about the source of the contamination or whether other drug products had been contaminated.

However, FDA acknowledges that, in the PAHO example, the international organization was working to promote and coordinate public health efforts rather than taking an enforcement role or harmonizing standards or requirements. Therefore, FDA has clarified the definition of ''international organization'' to extend to international organizations whose responsibilities include promoting and coordinating public health efforts, consistent with the Haiti example described in the preamble to the proposed rule.

FDA also points out that the World Health Organization (WHO), as well as PAHO (the WHO's regional body), does have a responsibility for harmonization and product standards.

4. Three comments also sought specifics as to which international organizations might be able to receive confidential commercial information from FDA under the rule. One comment suggested that FDA establish standards and procedures to determine which international organizations should receive confidential commercial information; the comment would have FDA identify such organizations through notice and comment rulemaking and require international organizations to give FDA a summary of their charters, purposes, membership, and internal rules for protecting confidential commercial information from public disclosure. One comment would permit FDA to disclose confidential commercial information only to international organizations whose regulatory responsibilities are established by law, treaties, or other acts of government, and would exclude private or nongovernmental organizations. Another comment would exclude nongovernmental organizations. The comment stated that employees of nongovernmental organizations may not be subject to any laws preventing unauthorized disclosures and might not be ''legally or morally bound'' to protect confidential commercial information provided by FDA.

Although FDA believes that many of the comments' suggestions would encumber the agency with excessive procedures and requirements, the agency agrees that the reference to international organizations should be more specific. The proposal was not intended to extend disclosures of confidential commercial information to private or nongovernmental organizations. Consequently, FDA has revised proposed § 20.89(e) so that the term ''international organization'' refers only to international organizations that are established by law, treaty, or other governmental action and that have the responsibility to facilitate global or regional harmonization of standards and requirements in FDA's area of responsibility or to promote and coordinate public health efforts. Thus, the international organizations subject to revised proposed § 20.89(e), therefore, are those that (unlike private or nongovernmental organizations) generally have statutes, regulations, or other obligations to protect confidential commercial information from public disclosure. Additionally, FDA will continue to require international organizations to provide written statements establishing their authority to protect confidential commercial information from public disclosure and written commitments not to disclose such information without the sponsor's written permission or written confirmation from FDA that the information is no longer confidential.

The agency declines, however, to amend the rule to establish notice and comment rulemaking procedures to determine which international organizations may be eligible to receive confidential commercial information from FDA. The agency reiterates that, in almost all cases, exchanges of confidential commercial information involve a sponsor's consent. Thus, the burdens on the agency associated with notice and comment rulemaking procedures for determining an international organization's ''eligibility'' to receive information outweigh any benefits from such procedures in this instance.

FDA also declines to amend the rule to create an explicit ''application'' to be submitted by international organizations. Currently, for all disclosures to State and foreign governments (including international organizations), FDA carefully examines the reasons why the requesting body needs confidential commercial information, the statutory and regulatory mechanisms for protecting information supplied by FDA, and the identities of persons who will receive the information. Requiring a summary of the international organization's charter, purpose, and membership could be done on a case-by-case basis, if necessary, but often would be unnecessary. The United States is a member of the international organizations that would generally be the recipients of information under the rule and, therefore, FDA already possesses information on their charters, purposes, and memberships. (For example, the United States is a member of the PAHO and the WHO, and information on their charters and memberships is readily available.) If an international organization requests confidential commercial information under § 20.89, and the United States is not a member of that organization, FDA will carefully review the request and will seek whatever documents it feels are necessary to evaluate the request.

5. One comment stated that developing countries that lack sophisticated health systems would be the countries most likely to rely on international organizations in a public health crisis. However, the comment explained, developing countries often lack intellectual property protections within their legal systems. The comment added that if confidential commercial information were ''routinely'' released to international organizations, there would be a corresponding increased risk of ''routine'' abuse of intellectual property protections worldwide, without any benefit to U.S. manufacturers or to the public health of the United States. The comment claimed that the rule would benefit only foreign organizations and foreign competitors to U.S. manufacturers.

The comment misinterprets the rule. Under § 20.89(c)(1)(i), a foreign government agency seeking confidential commercial information from FDA must provide both a written statement establishing its authority to protect confidential commercial information from public disclosure and a written commitment not to disclose such confidential commercial information ''*without the written permission of the sponsor* or written confirmation by the Food and Drug Administration that the information no longer has confidential status'' (emphasis added). Additionally, under § 20.89(c)(1)(ii)(A), FDA must determine that the sponsor of the product application has provided written authorization for the disclosure, or, under § 20.89(c)(1)(ii)(B), that disclosure would be in the interest of public health by reason of the foreign government's possessing information concerning the safety, efficacy, or quality of a product or information concerning an investigation. Under the final rule, these safeguards also would apply to disclosures of confidential commercial information to an international organization. FDA is not proposing, and has never proposed, to disclose confidential commercial information to a foreign government or to an international organization on a routine basis.

The agency notes that, under existing FDA regulations, an international organization that provides the necessary written statement and written commitment in order to obtain confidential commercial information from FDA cannot redisclose that confidential commercial information to a foreign government (or to any other party) without the sponsor's written permission or written confirmation from FDA that the information no longer has nonpublic status (see 21 CFR 20.89(c)(1)(i)). Thus, international organizations receiving confidential commercial information under this rule will not be conduits for disclosures of confidential commercial information to foreign governments without permission from the sponsor or from FDA. If an international organization intends to request confidential commercial information from FDA and then provide that information to a foreign government, both the international organization and the foreign government must provide the necessary written statements and commitments to FDA to ensure that the information is protected.

Moreover, as stated in the preamble to the proposed rule, in almost every case, disclosures of confidential commercial information to foreign governments have occurred with the sponsor's consent, and only after the foreign government has provided the necessary written statements (see 63 FR 40069 at 40070). Contrary to the comment's inference about the benefits that would flow to developing countries, the exchanges to date have been mostly to other developed countries. The disclosures have generally benefitted the sponsors of the confidential commercial information by facilitating approval or marketing decisions for the sponsor's product.

FDA further notes that it is conscious of intellectual property concerns, particularly for pharmaceuticals, and is quite aware of its obligation under Article 39.3 of the Agreement on Trade-related Aspects of Intellectual Property Rights to protect undisclosed test or other data against unfair commercial use. Article 39.3 requires governments to protect such data against public disclosure ''except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.'' The requirement in § 20.89(c)(1) for written statements and the general requirement for sponsor consent are intended to help protect confidential commercial information from unauthorized public disclosure.

6. Two comments stated that FDA should require or reaffirm that it will obtain a sponsor's consent before providing confidential commercial information to a foreign government or to an international organization. One comment would amend § 20.89(d)(1)(ii) to require written confidentiality agreements from international organizations and individuals in the organization who are to receive confidential commercial information and to require consent from sponsors.

FDA reiterates that neither the proposed rule nor this final rule changes the requirements for written statements, written commitments, and sponsor consent for exchanges involving confidential commercial information. The requirements for disclosures of confidential commercial information are found at § 20.89(c). The elimination of the written statement and written commitment requirement applies solely to exchanges involving nonpublic, predecisional documents under § 20.89(d). As stated earlier, nonpublic, predecisional documents are prepared by FDA and normally do not contain any confidential commercial information.

Thus, FDA declines to amend § 20.89(d)(1)(i) as suggested by the comment because that paragraph pertains to exchanges of nonpublic, predecisional information.

7. One comment would amend the rule to require a sponsor's consent for all disclosures of confidential commercial information to international organizations. The comment stated that FDA has no obligation to balance the public interest against a sponsor's interest in maintaining the confidentiality of information. The comment added that if FDA engages in such balancing of interests, it should provide written notice to the sponsor describing the confidential commercial information that has been provided to an international organization and, furthermore, that only the Commissioner of Food and Drugs (the Commissioner) should be authorized to make such disclosures to an international organization.

Similarly, another comment stated that if FDA discloses confidential commercial information to an international organization, without a sponsor's consent, under the ''public interest'' at § 20.89(c)(1)(ii), the agency should specify the public health circumstances justifying the disclosure.

When FDA first issued the final rule codifying § 20.89(c)(1)(ii) in 1993, it explained that there are situations in which it might be inappropriate to seek a sponsor's consent to a disclosure of confidential commercial information. The preamble to the 1993 final rule gave examples of possible situations in which a sponsor may have engaged in deliberate fraud or misrepresentation, or situations in which FDA might wish to share confidential commercial information obtained through an FDA investigation for a foreign government's use in its own regulatory efforts (see 58 FR 61598 at 61601 (November 19, 1993)). FDA stated that these types of disclosures to foreign government counterparts ''may facilitate efforts to keep unapproved, adulterated, counterfeit, or misbranded products off world markets as well as American markets.'' This rationale still applies, and, therefore, FDA declines to amend the rule to require a sponsor's consent in all disclosures of confidential commercial information.

As for the comments asking FDA to provide written notice to a manufacturer or to explain the public interest reasons behind a disclosure, FDA responded to similar comments in 1995 when it issued a final rule amending §§ 20.88 and 20.89. Those comments in 1995 suggested that FDA provide summaries of the information disclosed to foreign governments. In the preamble to the 1995 final rule, FDA stated that such summaries would be inappropriate or unnecessary (see 60 FR 63372 at 66379). FDA explained that if a foreign government were considering whether to take action against a particular product, requiring FDA to provide a summary to the product's manufacturer would alert the manufacturer to a potential enforcement action and would, therefore, be inappropriate. If FDA were helping a foreign government identify fraudulent goods and provided confidential commercial information to help distinguish legitimate products from fraudulent ones, providing a summary to the manufacturer would be unnecessary because the manufacturer would already know the information that was the basis of the summary.

FDA's rationale for not providing summaries also applies to the written notice and identification of the public health interests sought by the comments. If FDA were providing confidential commercial information to a foreign government to assist that government in a decision whether to take action against a particular product, providing a written notice to the product's manufacturer would alert the manufacturer to a potential enforcement action and might undermine or compromise the enforcement action. Similarly, stating that the public health interest involved an enforcement action would alert the product's manufacturer and might undermine or compromise any enforcement action. Thus, FDA

declines to revise the rule to require the agency to provide a written notice to a sponsor or to specify the public health interest reasons behind a disclosure.

As for the comment asking that the Commissioner be the only person authorized to disclose confidential commercial information to an international organization, FDA declines to amend the rule to impose such a limitation. The authority to disclose confidential commercial information under § 20.89 was delegated to the Associate Commissioner for Regulatory Affairs and various office and center officials (such as center directors and deputy directors) in 1994. Similar authority, for disclosures of confidential commercial information under § 20.88, was delegated in 1997. These delegations of authority have made exchanges of confidential commercial information with State and foreign government officials more efficient. Given the agency's experience with these previous delegations of authority, the agency sees no reason to limit or otherwise restrict the authority to disclose such information to international organizations.

8. One comment asked FDA to ''set out the means by which it can and will enforce any confidentiality agreement with an international organization.'' The comment said this information would be relevant to a sponsor's willingness to consent to releasing confidential commercial information to an international organization.

In previous rulemakings, FDA has stated that it would discontinue cooperative ventures with any State or foreign government that failed to honor its written commitment to protect the confidential commercial information provided by FDA (see 60 FR 63372 at 63377). The agency will extend this policy to cover international organizations receiving information from FDA.

The agency also notes that international organizations might cease to enjoy immunity and might face serious consequences if a person in the international organization made an unauthorized disclosure of confidential commercial information or if the international organization violated its written commitment. Under U.S. law, the President may, by Executive Order, designate certain international organizations as being entitled to the privileges, exemptions, and immunities that are normally afforded to foreign governments (see 22 U.S.C. 288). These privileges, exemptions, and immunities are significant, and include treatment comparable to that enjoyed by foreign governments as regards, for example, immunity from suit and judicial process (22 U.S.C. 288a), customs duties and taxes relating to importation (id.), and property taxes imposed by Congress (22 U.S.C. 288c). The President may revoke the designation of an international organization ''if in his judgment such action should be justified by reason of the abuse by an international organization or its officers and employees of the privileges, exemptions, and immunities provided * * *'' (id.) Thus, an international organization that failed to protect confidential commercial information would risk losing some or all of these significant privileges, exemptions, and immunities.

One should note that several international organizations that might conceivably request confidential commercial information from FDA are designated as international organizations under 22 U.S.C. 288. These include the Food and Agriculture Organization, PAHO (or PAHO/PASB (Pan American Sanitary Bureau)), and WHO.

Additionally, for officers and employees of international organizations, the immunity extends only to ''acts performed by them in their official capacity and falling within their functions * * * except insofar as such immunity may be waived by the foreign Government or international organization concerned'' (see 22 U.S.C. 288d(b)). An international organization official or employee who deliberately violates the organization's written commitment to FDA to protect confidential commercial information might not be considered to be acting within his or her ''official capacity'' or within his or her functions and, as a result, would not enjoy immunity from suit. For example, in *United States* v. *Enger*, 472 F. Supp. 490, 502 (D. N.J. 1978), a Federal district court rejected several defendants' claim that they could not be prosecuted for espionage because they were United Nations employees. The court stated, ''Espionage, the crime with which the defendants are charged, is, of course, not one of the functions performed in the defendants' official capacities with the United Nations'' (id.) (see also *Rendall-Speranza* v. *Nassim*, 107 F.3d 913, 920 (D.C. Cir. 1997) (plaintiff's failure to question a court's acceptance of the defendant organization's admission that its employee's act of battery was within the scope of his employment meant that the employee was immune from suit for battery under 22 U.S.C. 288d(b))).

International organizations that are not designated by an Executive Order do not enjoy the privileges, exemptions, and immunities as provided in 22 U.S.C. 288 through 288d. As a result, they, their officials, and their employees might not be immune from suit. In the event of an unauthorized disclosure of confidential commercial information, a sponsor would be able to pursue legal action against the undesignated international organization.

9. One comment stated that if an international organization requested confidential commercial information on an alleged health hazard, but the relevant foreign government had not asked for such information, FDA should consult the sponsor and allow the sponsor to handle any disclosure issues directly with the international organization. The comment added that if FDA were dissatisfied with the outcome between the sponsor and the international organization, FDA could release the data if it determined that a health hazard exists. The comment also stated that FDA should first determine that the international organization has responsibilities that require it to have the type of confidential commercial information requested.

FDA reiterates that, for almost all disclosures involving confidential commercial information to a State government, foreign government, or international organization, the sponsor's consent to disclosure will be obtained. However, the agency does not object to a sponsor's making individual disclosure arrangements with an international organization and agrees with the comment that, in some cases, the comment's approach would be practical.

Furthermore, disclosures under § 20.89 have been made on a case-by-case basis, and FDA will consider the foreign government's or international organization's need for the requested information when deciding whether to disclose information. The regulation is intended to facilitate communication with foreign governments and international organizations; it does not compel the agency to disclose confidential commercial information to a foreign government or to an international organization. Thus, if an international organization requests confidential commercial information without any apparent reason, FDA may decline to grant the request.

3. Editorial Changes

Proposed § 20.89(e) stated, in part, that for exchanges of confidential commercial information with an official of an international organization, the written statement and commitment ''shall be provided by both the

organization and the individual.'' FDA, on its own initiative, is replacing the words ''provided by'' with ''provided on behalf of'' to make the sentence more accurate because, in a literal sense, a document cannot be ''provided by'' an inanimate body such as an international organization. Instead, persons provide the required statements and commitments ''on behalf of'' the organization.

Additionally, §§ 20.88(e) and 20.89(d) authorize the Deputy Commissioner for Policy to authorize the disclosure of nonpublic, predecisional documents to State and foreign government officials. Because FDA has reorganized its offices, the functions that were handled by the then-Deputy Commissioner for Policy are now assigned to the Senior Associate Commissioner for Policy, Planning, and Legislation, and international policy functions that were in the then-Office of Policy are now assigned to the Office of International and Constituent Relations. Consequently, FDA is revising §§ 20.88(e) and 20.89(d) to refer to the Senior Associate Commissioner for Policy, Planning, and Legislation and to the Deputy Commissioner for International and Constituent Relations.

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. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a Federalism summary impact statement is not required.

V. Analysis of Impacts

FDA has examined the impacts of this final rule under Executive Order 12866, 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 new benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes this final rule is consistent with the regulatory philosophy and the principles identified in the Executive Order. In addition, this final rule is not an economically 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 final rule will have no significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act because it regulates only conduct of FDA, State and foreign governments, and international organizations, and not small entities under the Regulatory Flexibility Act. The final rule provides for FDA disclosure of 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. 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. The final rule also provides for FDA disclosure of nonpublic, predecisional documents and other nonpublic information created by FDA to State governments, foreign governments, and international organizations without the need to obtain written assurances. These beneficial effects outweigh any possible adverse impact. Thus, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities, and, under the Regulatory Flexibility Act, no further analysis is required.

The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector of $100 million (adjusted annually for inflation). This rule does not impose any mandates on State, local, or tribal governments, nor is it a significant regulatory action under the Unfunded Mandates Reform Act.

VI. Paperwork Reduction Act of 1995

This final 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.

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, 21 CFR part 20 is amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues 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) to read as follows:

§ 20.88 Communications with State and local government officials.

* * * * *

(e)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation, or the Deputy Commissioner for International and Constituent Relations, or any other officer or employee of the Food and Drug Administration whom the Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations may designate to act on their behalf for the purpose, may authorize the disclosure to, or receipt from, an official of a State government agency of nonpublic, predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of efforts to improve Federal-State uniformity, cooperative regulatory activities, or implementation of Federal-State agreements, provided that:

(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

(ii) The Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations or their designee makes the determination that the exchange is reasonably necessary to improve Federal-State uniformity, cooperative

regulatory activities, or implementation of Federal-State agreements.

* * * * *

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

§ 20.89 Communications with foreign government officials.

* * * * *

(d)(1) The Senior Associate Commissioner for Policy, Planning, and Legislation, or the Deputy Commissioner for International and Constituent Relations, or any other officer or employee of the Food and Drug Administration whom the Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations may designate to act on their behalf for the purpose, may authorize the disclosure to, or receipt from, an official of a foreign government agency of nonpublic, predecisional documents concerning the Food and Drug Administration's or the other government agency's regulations or other regulatory requirements, or other nonpublic information relevant to either agency's activities, as part of cooperative efforts to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements, provided that:

(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

(ii) The Senior Associate Commissioner for Policy, Planning, and Legislation or the Deputy Commissioner for International and Constituent Relations or their designee makes the determination that the exchange is reasonably necessary to facilitate global harmonization of regulatory requirements, cooperative regulatory activities, or implementation of international agreements.

* * * * *

(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 established by law, treaty, or other governmental action and having responsibility to facilitate global or regional harmonization of standards and requirements in FDA's areas of responsibility or to promote and coordinate public health efforts. For such officials, the statement and commitment required by paragraph (c)(1)(i) of this section shall be provided on behalf of both the organization and the individual.

Dated: December 3, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–5417 Filed 3–6–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Nicarbazin and Bacitracin Zinc

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Koffolk, Inc. The NADA provides for using approved nicarbazin and bacitracin zinc Type A medicated articles to make combination Type C medicated broiler chicken feeds used for prevention of coccidiosis and for increased rate of weight gain and improved feed efficiency.

DATES: This regulation is effective March 7, 2000.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067, filed NADA 141–146 that provides for combining approved Nicarb® (113.5 grams per pound (g/lb) nicarbazin) manufactured by Koffolk, Inc., and Baciferm® (50 g/lb bacitracin as bacitracin zinc) manufactured by Roche Vitamins, Inc., Type A medicated articles to make Type C medicated broiler chicken feeds. The Type C broiler feeds contain 113.5 g/ton (t) nicarbazin and 4 to 50 g/t bacitracin. The Type C broiler chicken feeds are used as an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency.

The NADA is approved as of February 2, 2000, and the regulations are amended by adding 21 CFR 558.78(d)(3)(xxi) and by amending the table in 21 CFR 558.366(c) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of Type A medicated articles to make combination drug Type C medicated feeds. Nicarbazin is a category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved Form FDA 1900 is required to make a Type C medicated feed from a category II drug. Under 21 U.S.C. 360b(m), as amended by the Animal Drug Availability Act of 1996 (Public Law 104–250), medicated feed applications have been replaced by a requirement for feedmill licenses. Therefore, use of Type A medicated articles to make Type C medicated feeds as provided in NADA 141–146 is limited to manufacture in a licensed feedmill.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows: