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Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Comments to: Bar Code Label Requirement for Human Drug Products and Blood, Proposed Rule; Federal Register Volume 68, Number 50, pages 12500-12534, Friday March 14, 2003
Docket 02N-0204

To whom it may concern:

Novartis Pharmaceuticals Corporation is a world leader in the research and development of products to protect and improve health and well-being. Novartis researches, develops, manufacturers and markets leading innovative prescription drugs used to treat a number of diseases and conditions, including central nervous system disorders, organ transplantation, cardiovascular diseases, dermatological diseases, respiratory disorders, cancer and arthritis. The company's mission is to improve people's lives by pioneering novel healthcare solutions.

As a global pharmaceutical corporation, Novartis is supportive of efforts to improve and to harmonize the technical requirements for registration of pharmaceutical products. We appreciate the opportunity to comment on this guidance in accordance with FDA's Good Guidance practices.

Novartis is generally in agreement with FDA's proposed rule regarding Bar Code Labeling. However, Novartis is concerned about the following key points:

1. estimation of regulatory impact/timing of FDA submissions and approvals. Novartis assumes that implementation of bar codes may require changes to some primary packaging materials or package configurations for some products, resulting in Supplemental filings to the Agency. To accommodate the increase in regulatory filings without impacting the proposed three-year implementation period, an expedited review category at the Agency is recommended for those packaging changes implemented to comply with the bar code initiative.
2. lack of a mechanism for exemptions to the bar code requirement. For some products or convenient package configurations, implementation of the bar code might require

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significant redesign resources, leading to decisions to discontinue the configuration. An exemption under defined conditions might allow certain configurations to remain.

These points are elaborated and additional comments are provided in the attached tabular format, for ease of FDA use.

These comments are being provided in written form and electronically as directed in the Federal Register Notice.

Novartis appreciates the opportunity to submit these comments and looks forward to continuing to work collaboratively with the Agency on this important initiative to enhance patient safety in the hospital setting by reducing medication errors.

Thank you for the opportunity to comment. If you have any questions, please contact me at 862-778-3379 or at e-mail: joan.materna@pharma.novartis.com.

Sincerely,

(signed in original)

✍Joan A. Materna

Global Regulatory CMC

Novartis Pharmaceuticals Corporation Comments on the Draft Bar Code Label Requirement for Human Drug Products and Blood; Proposed Rule; 68 Federal Register 12500 Guidance Docket No. 02N-0204

General Comments

1. Novartis Pharmaceuticals Corporation supports bar coding the packaging of unit of use pharmaceutical drugs used in hospital dispensing, to prevent medication errors. Consistent with our corporate philosophy, we wish to be recognized for having a positive impact on people's lives with our products, meeting customer needs and even surpassing external expectations.

2. In order to ensure success of bar coding the NDC code on our pharmaceutical products, Novartis believes revisions need to be made to the proposed rule. The suggested revisions are detailed below:

Subject	Comments
Linear Bar-code Requirement	Proposed 201.25(c)(1) would require the bar code for drugs and biological products (other than blood and blood products) to be any linear bar code in the UCC/EAN standard. The rationale behind limiting industry to the use of linear codes appears to be the cost of scanners and related equipment in the hospital sector. FDA states, "Some scanner manufacturers may be able to upgrade or modify an existing scanner to read newer symbologies, while other scanners, due to their age or the manner in which they were made, might not be capable of being upgraded. We invite further comment on this point." Novartis agrees with the proposal to utilize UCC/EAN standards; however, we believe the symbologies should not be limited to linear. As UCC/EAN standards are developed for newer technology symbologies (i.e., 2-D Data Matrix), the final rule should be worded to allow for their use. This flexibility is particularly relevant for particular packaging or product types as detailed later in these comments. The objective of the proposed rule is written as, "to enable the health care sector to utilize technological solutions to reduce preventable adverse drug events (ADEs) associated with medication errors in hospitals." It makes sense to permit the health care sector to make use of the best technological solutions that will be available to fulfill this goal. Limiting the industry to linear bar codes is contrary to the stated objective of the proposed rule. Novartis requests that FDA consider allowing industry to use any symbology for which the UCC/EAN has issued appropriate standards.
Lot Number / Expiration Date	Novartis agrees with the decision of the FDA to exclude the lot number and expiration date from the bar code requirement. The lot number and expiration date are not critical elements in reducing medication errors. Ensuring patients receive the right drug and right dose can be accomplished with scanning a bar code containing the NDC number only. The regulation should permit the inclusion of Lot and Expiration Date information.

Exemptions	The FDA decision to exclude exemptions is of concern to Novartis. Although we fully support bar coding of all unit-of-use packaging, there are unique packages and/or products that would require package re-design to meet the requirement. We believe the exemption is critical as some pharmaceutical companies may decide to discontinue products (or convenient package configurations) that pose technical difficulty rather than pursue re-design that would require costly testing and stability studies. An example of required package redesign would be suppository packaging. In many cases, a suppository unit dose is not capable of accommodating a high quality bar code. Another example is small ophthalmic containers. For ophthalmic products, re-evaluation of current ink systems, label structure or inclusion of a dark color (required for scanning bar codes) will require label / ink compatibility testing. In both examples, the packages cannot accommodate a high quality bar code due to materials of construction and/or size restrictions. The support of a bar code would require new materials (product contact) or an increase in package size. Primary (product contact) packaging components are tightly scrutinized through testing and stability studies. Changing primary components to accommodate a bar code requires extensive testing and in some cases long term stability studies. For example, if increasing the small ophthalmic (small bottles) container size is the only option for complying with the proposed bar code rule, manufacturers may be forced to provide more solution (drug) than required for a specific treatment or dose regimen. Increased cost for manufacturing and patient compliance may result. Prior to implementation, FDA approval for changes in primary packaging and contact surfaces is generally required. In addition, changes to primary components that are Child-Resistant (i.e. peel-push blisters) will require testing be performed to ensure compliance with the Poison Prevention Packaging Act. Should the component change adversely affect the Child-Resistant feature, further design changes would be required. Novartis agrees with the FDA comments that a blanket small package exemption is not appropriate. A blanket exemption may hinder innovation that could ultimately lead to the ability to print high quality barcodes on all packaging, an example being two-dimensional codes. Novartis supports an exemption provision that would be handled on a case by case basis. A pharmaceutical company would need to request a waiver from the FDA with supporting data to demonstrate why the requirement cannot be reasonably met for a certain product/package. This waiver would only be used for product/packages that currently cannot meet the requirement. Future product/packages will have the bar-code requirement included in the design.
Regulatory Impact	Based on the requirements for material selection, evaluation, testing and stability studies for all products that require primary package changes, a reasonable assumption can be made that Novartis would file several Prior Approval and/or Changes Being Effected Supplements during the last year of the three year implementation period. Given that all companies will face similar situations require packaging re-design, it can be assumed that many Supplements will be filed with the FDA during the final year. Novartis is concerned that this dramatic increase in regulatory filings will create delays with approvals, thus hindering industry's ability to meet the three year implementation period. Novartis requests that the Agency consider an expedited submission category for packaging changes implemented in

	order to comply with the bar code initiative. In addition, Novartis assumes that the updated label text will need to be submitted to FDA illustrating the "administrative" type change related to the new bar code design, and that this change may be submitted in the Annual Report when implemented. The regulation should specify that this is the case, and that a separate submission is not required.
Unit-Dose Package Labeling Requirement	Novartis is working on the implementation of bar coding of solid oral dosage blister packaging and has performed printing trials in support of this effort. The test results show that small blister packs present challenges due to the labeling regulations provided in 21CFR Part 201.1 and Part 430.100. These regulations minimally require the Product Name, Strength, Expiration Date, Lot Number, Name of Manufacturer or Distributor, and NDC code (optional but will be present as human readable with barcode). Depending on the type of drug product, statements such as "Protect From Light" and "May Be Habit Forming" are also required. Excluding of some of this information will provide a greater probability for success of printing high quality bar codes on unit-dose blisters. Specifically, exclusion of the Manufacturer or Distributor's name and address is requested. The NDC bar code will provide the link for a hospital to determine the Manufacturer or Distributor. Novartis strongly believes the FDA should include specific wording in the final rule on the labeling requirements for unit-dose blisters subject to the bar code requirements. This will reduce misinterpretation of labeling requirements and allow faster implementation of bar codes on unit-dose blister packaging.
Economic Impact	Novartis believes the FDA has underestimated the costs associated with the proposed rule for both industry and the health care sector. In order to print high quality bar codes, new or upgraded equipment will be purchased. If some packages are re-designed to meet the regulation, costly tests, validation, and stability studies will also be required. Novartis is prepared to make the necessary investments to reduce medication errors.
Three Year Implementation Period / NDC Regulation Change	Novartis does not believe shortening the implementation period will be of significant benefit as the vast majority of hospitals are not presently ready to utilize bar codes to reduce medication errors. The three year period is adequate provided an exemption or waiver system is included in the final rule. Also, FDA has stated its intent to "revise the drug establishment registration and listing regulations to redefine the NDC number..." This redefinition may affect every drug distributed by Novartis and will draw on the same resources needed for bar code implementation. Novartis does not see merit in moving forward to execute the bar code initiative until the new NDC regulations are published. It is difficult to comment on how these two regulations would best be implemented, together or separately, without an understanding of the requirements of the new NDC regulations. It may be best to have an implementation period for the bar code regulation distinct from and subsequent to that of the new rule on NDC number assignment and drug listing.