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April 10, 2003

Office of Information and Regulatory Affairs
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: 21 CFR Parts 201, 606, and 610, [Docket No. 02n-0204] Proposed Rule
Bar Code Label Requirements for Human Drug Products and Blood Information Collection

Dear Mr. Shapiro:

Hollister-Stier Laboratories LLC (Hollister-Stier), a small business entity, is submitting written comments regarding the information collection requirements for the proposed rule "Bar Code Label Requirements for Human Drug Products and Blood" listed in the March 14, 2003, Federal Register. 68 Fed. Reg. 12,500. Hollister-Stier Laboratories intends to submit more detailed comments regarding the substance of this proposed rule by June 12, 2003.

Hollister-Stier is a licensed biologics manufacturer of allergenic extracts. Allergenic extracts are indicated for use by experienced physicians (allergists) in diagnosis and treatment of patients presenting symptoms of allergy to specific environmental allergens. Following diagnosis by skin testing, a patient-specific formulation is compounded to include various allergens. Dosage of allergenic extracts is a highly individualized matter and varies according to the degree of sensitivity of the patient and various other factors.

The FDA is proposing a new rule that would require certain human drug product labels and biological product labels to include bar codes. The proposed rule calls for the use of a linear bar code that would contain the drug or biological product's National Drug Code (NDC) number. The proposed rule is designed to reduce the number of medication errors in hospitals and other health care settings, by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

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Hollister-Stier recognizes the value of applying bar coded labels to help reduce medication errors in hospital settings. Allergenic extracts are unique products, however, and the proposed rule places onerous and unnecessary burdens on manufacturers of such products. These comments are intended to address the proposed rule's information collection requirements. A basic understanding of the proposed rule's substantive impact on Hollister-Stier's operations is required, however, to fully appreciate the onerous nature of its information collection requirements when applied to manufacturers of allergenic extracts.

- First, the proposed rule would require bar coding for human prescription drugs and OTC drugs dispensed under an order **and commonly used in hospitals**.

  Allergenic extracts are sold directly to physicians (allergists) who specialize in the diagnosis and treatment of allergies, in private office or clinic settings. Allergenic extracts are not commonly dispensed or administered in a hospital setting. Allergists use allergenic extracts to test and desensitize patients by formulating custom mixtures that are specific to a patient. These allergenic extract prescription mixtures may consist of one to 20 or more allergenic extracts, with variable concentrations, dosages, and schedules that are unique to a specific patient.

  FDA itself has observed that bar coding drug products distributed directly to physicians' offices will serve no meaningful purpose. The agency stated in the proposed rule that it "decided to omit prescription drug samples from a proposed bar code requirement because most samples are given to patients at physicians' offices." FDA reasoned that "[b]ecause [it has] no evidence to suggest that physicians' offices are likely to be equipped with bar code scanners in the immediate future, the benefits associated with preventing medication errors through bar codes on prescription drug samples are unlikely to be realized in this health care setting." 68 Fed. Reg. at 12,505.

- The proposed rule would also require the NDC Numbers to identify at a minimum, each drug product, dosage, strength, nature and form. This NDC number must be applied to both the product label and, to be visible, would be included on the box containing the product.

  Hollister-Stier currently does not have NDC Numbers for each extracted allergen source material (allergenic extract). FDA has allowed generic groupings for allergens under one NDC code for the Allergenic Extract industry. Hollister-Stier, for example, has more than 75 Pollen Glycerin Extracts listed in its product catalog. The NDC number assigned to this group of allergenic extracts is 65044 (labeler code)-9950 (Product Code)-0 (Packaging Code).

  Hollister-Stier actively markets approximately 200 allergens with at least 4 package configurations for each. Under the proposed rule, we would be required to assign an

individual NDC number to each unique allergenic extract, which could include more than 800 new NDC numbers. The large number of Hollister-Stier extracts and new NDC numbers required under this proposed rule is sharply at odds with the agency's assumptions and expectation, and would have enormous information generating and collection implications for both Hollister-Stier and FDA.

With respect to the proposed rule's information collection provisions, FDA has specifically invited comments to the following questions.

1- **Whether the collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility.**

The proposed rule would not enhance FDA's oversight of the allergenic extract industry and would not have the intended effect of reducing medication errors. These extracts are administered to patients in a clinic or physician's office setting where mistakes do not normally occur. Additionally, by FDA's own admission, physicians' offices are not likely to have bar code readers.

2- **The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.**

FDA estimates that the cost of compliance will be $600 for small businesses that manufacture biological products. 68 Fed. Reg. at 12,528. This estimate is not accurate. Hollister-Stier is defined as a small business (under 500 employees). As noted above, we would need to add more than 800 new NDC Code numbers to our product labels and packaging.

We have discussed this issue with our current vendor and have determined that because of the small size of many of our labels, the addition of a bar code would require a flag label attachment in order to include the bar code information. Our current vendor cannot provide this type of label, therefore, there would be an increased cost to locate and set up a new vendor. In addition, we understand that only a very small number of vendors are able to produce these flag attached labels.

We have attempted to estimate some of the start up costs that Hollister-Stier would incur if required to comply with the proposed bar code rule:

$37,000 for the required equipment and artwork to add bar codes to labels and boxes, e.g. artwork plates, label dies, bar code readers, and new inkjet printers for box printing. This equipment would need to be purchased for both Hollister-Stier for labels produced internally, and for our various outside vendors who produce labels and boxes.

$39,000 for approximately 640 hours of computer programming time for testing and validation of the new label format.

$17,000 for Inventory Control, Purchasing, and Regulatory personnel time for internal control of each label/package change which is required per procedure. This cost includes an estimate of more than 530 hours at $31 per hour.

$18,000 for Standard Operating Procedure changes, which includes personnel time for changing, routing, review and approval of more than 12 procedures.

Unknown but substantial for costs of special flag labels with bar codes. Hollister-Stier's current costs for traditional labels are approximately $4,000. Our current vendor is unable to supply a cost estimate, but we anticipate the costs for the flag labels with bar codes could exceed the current expenditure by three or four times.

The above cost estimates are conservative because they do not include an estimate of additional labor costs for box set up, additional Quality Assurance and Regulatory Release labor costs, or additional production costs on an annualized on-going basis.

Other costs not calculated at this time include enlisting consultants in bar coding, necessary to offer guidance and understanding with regard to the bar code process. Accordingly, we anticipate that complying with the proposed bar code requirement could cost Hollister-Stier more than $120,000, well in excess of the agency's estimated cost of $600.

3- **Ways to enhance the quality, utility, and clarity of the information to be collected.**

The proposed rule would require manufacturers to report label changes to FDA on an annual basis, which for Hollister-Stier, would initially entail the submission of sample labels and boxes for each of its 800 labels and 800 boxes. FDA's estimate indicated that each report for one label takes 1 minute. The Hollister-Stier estimate for this process is 15 minutes per individual label report, or approximately 400 hours.

We also point out that Hollister-Stier, over the last three years of Annual Reporting, has submitted some 30 product labels per report, a number that greatly exceeds the agency's estimate of one product per establishment for biological product manufactures, as noted in Table 1 of the proposed rule. 68 Fed. Reg. At 12,516.

Clearly this requirement will place an onerous and unnecessary burden on Hollister-Stier and the agency.

4- **Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms for information technology.**

Hollister-Stier is a small business not presently equipped to perform electronic submissions of data, e.g. electronic submissions of label copy.

In closing, we have summarized in general terms the additional burdens that imposing the proposed bar coding rule on Hollister-Stier would have on our manufacturing business. We estimated that complying with the proposed rule will impose an initial, additional financial burden in excess of $120,000, and will consume over 1500 hours of personnel time. A small business like Hollister-Stier cannot bear such a burden. In addition, we note that the benefits associated with preventing medication errors through the use of bar codes are unlikely to be realized if the rule is imposed on the allergenic extract manufacturers. Hollister-Stier's products are not commonly dispensed to hospitals, but rather are distributed to physician's offices. As FDA noted in the proposed rule, physicians are not likely to be equipped with bar code scanners in the immediate future. Accordingly, the intended objective of the proposed bar coding rule will not be attained in the allergenic extract industry.

Please contact me by phone at 1-509-482-1721 or email at david_mirabell@hollister-stier.com should you have any questions.

Sincerely,

David L. Mirabell
Director, Regulatory Affairs and Professional Services

DLM/GKB

TRANSMISSION VERIFICATION REPORT

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