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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)
Bar Code Label Requirements for Human Drug Products
and Blood Information Collection

Dear Mr. Shapiro,

Allergy Laboratories, Inc., is a licensed biologics manufacturer of allergenic extracts and a small business entity with 30 employees. The following is our written comments regarding the information collection requirements for the above referenced proposed rule as posted in the March 14, 2003, Federal Register 68 Fed. Reg. 12,500.

As you may be aware allergenic extracts are used by physicians for the diagnosis and treatment of patients with symptoms of allergy to specific environmental allergens and foods . Following diagnosis, a patient specific formulation is compounded either by the doctor with our bulk extract or by us, to include those allergens identified as the offending agents. The treatment formulation then is uniquely theirs. Furthermore, several dilutions may be compounded for each patient and the treatment varies according to each patients sensitivity as well as other considerations.

While one could logically come to the conclusion that the proposed rule may only apply to hospitals and other interned care facilities and not physicians' offices we thought it best to voice our objections in a timely manner and to ask the agency for clarification in this regard. The FDA itself has stated the bar coding of drug products distributed directly to physicians offices will serve no meaningful purpose. Additionally, in the proposed rule it has omitted prescription drug samples from the proposed bar code rule because most samples are given to patients at the physicians' offices. Furthermore, the FDA has stated 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 12505. While our products are certainly not free drug samples they are nevertheless dispensed in the physician's office.

The proposed rule would also require the NDC numbers to identify at a minimum, each drug product, dosage, strength, nature and form. The NDC number must be applied to both the product label and, to be visible, included on the box containing the product. Allergy Laboratories currently does not have NDC numbers for the 300+ allergens as the FDA has allowed for generic groupings of allergens under one NDC code for the Allergenic Extract industry. Allergy Laboratories currently markets a little over 300 different allergens in 4 different package configurations. This translates into over 1200 individual NDC numbers. The proposed rule should address this by exempting allergenic extracts and their dilutions from this rule.

The 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.

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We do not believe the proposed rule would enhance the FDA's oversight of the allergenic extract industry and would not have the intended effect of reducing medication errors. By the FDA's own admission, physicians' offices are not likely to have bar code readers. We have not been furnished nor seen any evidence that the collection of this information is necessary or will have any practical utility for the proper performance of the FDA's functions as it applies to allergenic extracts.

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

The FDA's estimate that the cost of compliance will be $600 for small businesses that manufacture biological products is woefully inadequate. In our small business we would need to add more than 1200 new NDC code numbers to our product labels and packaging at a staggering cost of some ***$166,500***. Furthermore, we believe there are unknown, but substantial, hidden costs required due to the small nature of some of our final containers requiring special bar code labels. We do not believe that allergenic extracts were considered when the agency calculated its 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 Allergy Laboratories, would initially entail the submission of sample labels and boxes for each of its 1200 labels and 1200 boxes. FDA's estimate indicated that each report for one label takes 1 minute. Our estimate is a minimum of 10 minutes per individual report. This works out to over 400 man hours for our 1200 labels and boxes. This will place unnecessary hardships on our small company as well as fail to enhance the quality, utility and clarity of the information to be collected. We believe there is an equal chance the opposite of the desired effect will occur in the allergenic extracts arena due to the voluminous codes generated and the corresponding need to disseminate this information to each and every physician and the compliance problem therein.

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.

While they may be novel approaches to minimizing the burden of the collection of information from respondents we do not have the resources to explore these avenues.

In closing, we believe that allergenic extracts and their dilutions should be exempted from this proposed rule. In the alternative the rule should be amended to specifically exclude allergenic extracts and their dilutions delivered to physicians' offices or clinics.

Sincerely,
Allergy Laboratories, Inc.

Warren Johnson
Vice-President