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January 30, 2003

Jennie C. Butler
Dockets Management Branch
Food and Drug Administration (HFA-305)
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20817

Re: **Docket No. 02N-0486**; Agency Information Collection Activities, Prescription Drug Marketing Act of 1987; 67 Fed., Reg. 71574 (Dec. 2, 2002).

Dear Ms. Butler:

We are counsel to the National Association of Free Clinics, representing the volunteer local healthcare providers that are the first to see a growing number of the unemployed or the employed uninsured. These Free Clinics are staffed by volunteer physicians and other health care professionals and supported in the main by donations of money, services and sample pharmaceuticals from the local community – neighbors helping neighbors in need. These Free Clinics have come to rely upon the prescription drug samples donated from local physicians and clinics in the delivery of healthcare to their patients.

In a final rule promulgated December 3, 1999, in Docket Nos. 92N-0297 and 88N-0258, FDA imposed substantial recordkeeping requirements on Free Clinics and other charitable institutions which receive donated prescription drugs from physicians and clinics. These requirements are codified at 21 CFR Sec. 203.39. The Free Clinics want the Office of Management and Budget to know that these same requirements do not apply to those who first receive donated samples directly from pharmaceutical companies – i.e., doctors, hospital pharmacies and even charitable clinics.

02N-0486 C 3

After they first heard of these regulations the Free Clinics sought some relief from the FDA because Free Clinics simply do not have the resources to divert from patient care to recordkeeping. FDA granted some relief at the end of the year 2000 and met with Free Clinic representatives in June of 2001. The result was that FDA issued a Draft Guidance for industry in June of 2002 (enclosed herewith) that states that FDA will not be enforcing the provisions of 203.39 except in cases of fraud or other illegal conduct. Since that time, FDA has engaged a contractor to make a study and to obtain information about the potential burdens on Free Clinics as well as the risks of diversion from Free Clinics that the regulations seek to protect against. The Free Clinics are cooperating with the FDA's contractor in its quest for information. The Office and Management and Budget needs to know that these regulations are subject to an enforcement moratorium.

In its December 2, 2002 Federal Register notice on the proposed collection of information, FDA asked for comment on the accuracy of FDA's estimate of the burden that is imposed by recordmaking and recordkeeping requirements of the regulation. In this regard, FDA set forth two proposed Tables (2 and 3) in the Federal Register notice which, in the Association's view, grossly underestimate the frequency of the recordmaking that these charitable institutions would have to perform under 21 CFR Sec. 203.39. The principal error is in the FDA's estimate that the respondents would make the records required under 21 CFR Sec. 203.39(e) and (f) only one time per year. This would not be the case since the samples may be donated on a weekly or more frequent basis. Corresponding changes in the burden estimates for recordkeeping under 21 CFR Sec. 203.39 should be made.

In its December 2, 2002 Federal Register notice, FDA also asked whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility. In various letters and in meetings with FDA, the Free Clinics have shown how these regulations would have a devastating impact on Free Clinics and their efforts to deliver patient care at no cost. In so stating, FDA and the Office of Management and Budget should be aware that since PDMA was enacted, the Free Clinics have received donated and distributed free samples and there have been no known incidences of diversion.

All of the above information should be brought to the attention of the Office of Management and Budget as well.

Thank you very much for your consideration of this comment.

Sincerely yours,

Anthony L. Young
General Counsel
National Association of Free Clinics

Attachment

cc: Glenn T. Pierce