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June 12, 2003

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

Re: Docket No. 02N-0204: Proposed Regulation on Bar Code Label Requirement for Human Drug Products and Blood

Dear Sir or Madam:

The Committee on Health Care of the Council on Radionuclides and Radiopharmaceuticals ("CORAR") respectfully submits these comments on the above-referenced proposed regulation, which was published by the Food and Drug Administration ("FDA") in the Federal Register of March 14, 2003.[1] CORAR is an industry association of manufacturers of radiopharmaceuticals, radionuclides, radiochemicals, and other radioactive products primarily used in medicine and life research. The member companies of CORAR supply radiopharmaceuticals and radioactive materials to physicians and research facilities throughout the world. Radiopharmaceuticals manufactured by CORAR members are used in over 14 million medical procedures each year in the United States, predominantly for diagnostic and monitoring applications, but also for therapeutic use.

02N-0204

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[1] 68 Fed. Reg. 12500.

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CORAR generally supports FDA's proposed bar code regulation and, as explained below, urges FDA to preserve the exemption the regulations provide for certain pharmacies.

I. BACKGROUND

A. Nuclear Pharmacies

Although some radiopharmaceuticals are shipped directly by manufacturers to hospitals and other providers that perform nuclear medicine procedures, most radiopharmaceuticals are dispensed by nuclear pharmacies. Nuclear pharmacies enable radiopharmaceuticals with short half-lives to be prepared in final dosage form shortly before they are to be administered to patients. Nuclear pharmacies typically purchase non-radioactive kits from manufacturers. The kits contain all of the necessary ingredients for a radiopharmaceutical except the radionuclide. The nuclear pharmacy reconstitutes and adds a radionuclide to the kit according to the manufacturer's instructions, and ships the resulting radiolabeled drug to the hospital or other health care provider that will perform the nuclear medicine procedure.

Because nuclear pharmacies operated by members of CORAR are regularly engaged in dispensing radiopharmaceuticals upon the order of medical practitioners, and engage in preparing radiopharmaceuticals only in the regular course of their business of selling drugs at retail, the pharmacies are exempt from the establishment registration requirement under section 510(g) of the Federal Food, Drug, and Cosmetic Act ("FDC Act").

B. Requirements of the Proposed Regulation

FDA's bar coding proposal would require the labels of certain human drug and biological products to bear a bar code, which "would provide unique, identifying information about the drug that is to be dispensed to the patient."[2] The proposal would require a bar code on the labels[3] of "[p]rescription drug products (excluding samples),

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2 Id. at 12502.

3 The bar code would have to appear both on the "immediate container label as well as the outside container or wrapper, unless the bar code is easily legible and machine-readable through the outside container or wrapper." Id. at 12511; see also Federal Food, Drug, and Cosmetic Act § 201(k) (defining "label").

biological products, and over-the-counter drug products that are dispensed under an order and are commonly used in hospitals."[4]

Only manufacturers, repackers, relabelers, and private label distributors of human prescription and OTC drug products would be subject to the bar code requirements.[5] However, entities that are exempt from the registration and drug listing requirements in Section 510 of the FDC Act would not be required to comply with the rule.[6] Accordingly, the nuclear pharmacies operated by CORAR members would not be required to put bar codes on the labels of radiopharmaceuticals they prepare and ship to health care providers.

II. NUCLEAR PHARMACIES SHOULD REMAIN EXEMPT FROM THE PROPOSED REGULATIONS

CORAR urges FDA to maintain the bar code exemption for nuclear pharmacies that are exempt from the FDC Act's registration and drug listing requirements. Requiring nuclear pharmacies to place bar codes on the radiopharmaceuticals they prepare would not further the goals of the regulation and could subject nuclear pharmacy employees and hospital personnel to additional radiation exposure.

The proposed rule would require bar codes to appear on the immediate container label and the outside container label of human drug and blood products.[7] The immediate container in the case of a radiopharmaceutical prepared by a nuclear pharmacy is a syringe or vial. In a nuclear pharmacy, bar codes on radiopharmaceutical syringes and vials would have to be verified for quality control, and this verification process would subject nuclear pharmacy employees to additional radiation exposure. Furthermore, hospital and clinic workers who would have to scan the bar codes on the syringes and vials would also be subject to additional radiation exposure.

In addition to the radiation exposure problem, a bar coding requirement would impose significant new costs on certain nuclear pharmacies. The outside containers of radiopharmaceuticals are lead "pigs," which encase the syringes and vials and are used to ship the radioactive materials. The lead pigs are recycled due to their significant cost.

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4 68 Fed. Reg. at 12534 (proposed 21 C.F.R. § 201.25(b)).

5 Id. at 12534 (proposed 21 C.F.R. § 201.25(a)).

6 Id.; see also id. at 12503.

7 Id. at 12511.

Therefore, any bar codes used on them would have to be removable. For certain nuclear pharmacies, a requirement to place a removable bar code on the recyclable lead pigs would require new labeling or shrink wrapping equipment, which would impose a significant financial burden on these pharmacies.[8]

In the case of radiopharmaceuticals, the costs of the proposal in terms of risk of increased radiation exposure and additional pharmacy equipment expenses are not justified in view of the already extremely low misadministration rate. A five-year analysis of the effectiveness of the Nuclear Regulatory Commission's ("NRC's") Quality Management and Misadministration Rule found the net number of reported therapy misadministrations for radiopharmaceuticals to be approximately 30 to 40 per year.[9] Similarly, in the NRC's Annual Performance Report, the Commission noted that there were only 32 reportable "medical events" in 2002.[10] In its draft annual report to Congress, the NRC noted that there were only four misadministrations of radiopharmaceuticals that qualified as "abnormal

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8 Subjecting nuclear pharmacies to the proposed bar code regulations would also require nuclear pharmacies to obtain a Nuclear Regulatory Commission ("NRC") or Agreement State license amendment in order to add bar codes to the labels of radiopharmaceuticals. Licensing authorities generally require as a condition of the license that all proposed labeling changes be approved by the licensing authority.

9 Memorandum from Hugh L. Thompson, Acting Executive Director, Operations, NRC, to NRC Commissioners (Feb. 12, 1997), http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1997/secy1997-037/1997-037scy.html.

10 NRC, Performance and Accountability Report – Fiscal Year 2002, Chapter II, Nuclear Materials Safety, http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1542/v8/perf_account_2002.html#materials (last visited June 9, 2003); see also Memorandum from William D. Travers, Executive Director for Operations, NRC, to NRC Commissioners (Apr. 5, 2002) (providing data from the NRC Nuclear Materials Events Database from 1996-2001), http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2002/secy2002-0064/2002-0064scy.html.

Reportable "medical events" consist primarily of misadministrations of radioactive drugs but may also include other events, such as a leaking sealed source. Medical events must be reported to the NRC under 10 C.F.R. § 35.3045.

occurrences" in 2002.[11] The number of diagnostic nuclear medicine procedures in the U.S. in 2002 is estimated to have been over 14,336,000, and this does not include therapeutic procedures.[12] When compared with this figure, 30 to 40 misadministrations are insignificant, and are a far cry from the 7-20 percent medical error rate for conventional drugs that FDA noted in the preamble.[13]

III. CONCLUSION

Imposing a bar coding requirement on nuclear pharmacies would provide little benefit to justify the risks and costs described above. Accordingly, CORAR supports the proposed regulation's exemption for entities that are exempt from FDA registration and drug listing requirements and urges the Agency to preserve this exemption, at least with regard to nuclear pharmacies.

Respectfully submitted,

Alan M. Kirschenbaum
Counsel to the Council on Radionuclides and Radiopharmaceuticals

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11 An "abnormal occurrence" is an "unscheduled incident or event" that the NRC determines to be significant from a public health or safety standpoint. 42 U.S.C. § 5848. See NRC, Draft Report to Congress on Abnormal Occurrences Fiscal Year 2002 at iii (March 2003), http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1997/secy1997-037/1997-037scy.html.

12 Biotech Systems, Inc., U.S. Market for Diagnostic Radiopharmaceuticals (Report No. 150), April 2003, Exhibit 1-6 at 3.

13 68 Fed. Reg. at 12501.