

### Hospital Pharmacy and the CGMP: Additional Comments

In their response<sup>1</sup> to Dr. Feldmann's editorial<sup>2</sup>, Dr. Belson and Dr. Loftus claimed that, in FDA's view, the guidelines issued by the American Society of Hospital Pharmacists in the December 1977 issue of the *American Journal of Hospital Pharmacy* are suitable equivalents to the CGMP's for normal hospital pharmacy practice and that Dr. Kennedy has endorsed those guidelines. What is a normal hospital pharmacy practice? Furthermore, one of these guidelines is: "In the absence of valid stability data, an arbitrary expiration date of not more than 60 days from the date of repacking, or as defined by the FDA or USP, should be used."

In an earlier response<sup>3</sup> to Dr. Feldmann's editorial, I reported that some drugs that are being repackaged in hospital pharmacies are not stable even for 30 days. How could one go by an arbitrary expiration date of 60 days? Incidentally, the above guidelines do state that if stability data are available, the data should be used to determine the expiration date. The data on the products that were not stable even for 30 days were not available to justify an expiration date of less than 60 days, that is, less than 60 days of the arbitrary date as suggested by the above quoted guideline.

In the February 1979 issue of the *American Journal of Hospital Pharmacy*, the Society revised this guideline and deleted the arbitrary expiration date of 60 days. The new guideline is: "It is the responsibility of the pharmacist, taking into account the nature of the drug repackaged, the characteristics of the package and the storage conditions to which the drug may be subjected, to determine the expiration date to be placed on the package. This date must not be beyond that of the original package."

This guideline is far better than the original one. However, how many hospital pharmacists are determining the expiration dates by actual data! Perhaps less than 1% of those who are engaged in repackaging drugs.

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<sup>1</sup> J. J. Belson and B. T. Loftus, *J. Pharm. Sci.*, 68 (8), IV (1979).

<sup>2</sup> E. G. Feldmann, *ibid.*, 68 (5), I (1979).

<sup>3</sup> V. D. Gupta, *ibid.*, 68 (7), IV (1979).

### Faculty Position in Clinical Pharmacy at the Assistant Professor Level

Applications are invited for a full-time appointment, effective January 1, 1980.

The position requires the Pharm.D. degree and recent clinical experience. Responsibilities include didactic and clerkship instruction within the Clinical Pharmacy component of the curriculum; and participation in the laboratory component of the course in Professional Pharmacy Practice.

A strong commitment to participation in the College's Continuing Education efforts is vital.

Interested candidates should send a letter of application, curriculum vitae and the names of three references to: **Abraham J. Haddad, Ph.D., Dean, Hampden Campus, Massachusetts College of Pharmacy & Allied Health Sciences, 24 Bellamy Road, Springfield, MA 01119.**

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Please direct resumes and inquiries to **Dr. Harry B. Kostenbauder, Associate Dean, College of Pharmacy, University of Kentucky, Lexington, Ky 40506.**

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### Faculty Positions: Pharmaceutics and Industrial Sciences

The Arnold & Marie Schwartz College of Pharmacy and Health Sciences (formerly Brooklyn College of Pharmacy) in New York City is expanding its faculty in the Division of Pharmaceutics and Industrial Sciences. Only those individuals with a proven record of research leading to publication in recognized scientific and professional journals should apply.

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Applicants are invited to submit their credentials, including references to: **Dr. Anthony J. Cutie, Director of the Division of Pharmaceutics and Industrial Sciences, Arnold & Marie Schwartz College of Pharmacy and Health Sciences of Long Island University, 75 DeKalb Avenue at University Plaza, Brooklyn, New York 11201.**

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