DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

October 23, 1997

Ms. Kim Shroeder
Dey Laboratories, Inc.
2751 NAPA Valley Corporate Drive
NAPA, CA. 94558

Dear Kim:

Regarding your newly purchased products, EPIPEN and EPIPEN-EZ, product numbers 0301-01, 0302-01, 0303-01 and 0304-01 under labeler number 00268, I have been in contact with Mr. Herb Gerstenzang, FDA in order to determine the Drug Category for you to use when reporting them to us. Because these products are included in a package with a new delivery system, they are listed by the FDA under an NDA (New Drug Application). The products themselves, however, are listed under an ANDA (Abbreviated New Drug Application) because they are very old products and made by many generic drug companies.

After having a discussion with Herb, we determined that, even though the current NDCs of these products (00268-0301 through 0304) are listed under an NDA, it is entirely fitting and proper for you to report them to the Drug Rebate Program with a Drug Category of "N" (Non-innovator, Multiple Source) and be subject to the lowest rebate amount of 11% of quarterly AMP.

Should you have any further questions regarding this decision or would require additional documentation, please do not hesitate to call me at (410) 786-3314.

Sincerely,

Vincent G. Powell
Senior Health Insurance Specialist
Medicaid Drug Rebate Program
HCFA/CMSO/DSG/DSS