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June 12, 2003

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

Dear Madam or Sir:

AdvancePCS appreciates this opportunity to submit comments in regard to the Food and Drug Administration's proposed rule on bar code labeling for human drug products and blood. We commend the FDA for the extensive research and consultation conducted in developing this proposed rule.

AdvancePCS (www.advancepes.com) is one of the nation's largest pharmacy benefit managers (PBMs) providing services to more than 75 million health plan members and managing approximately \$28 billion in annual prescription drug spending. AdvancePCS offers health plans a wide range of health improvement products and services designed to improve the quality of care delivered to health plan members and to manage costs.

Providing services that make prescription drug benefits more affordable and, prescription drug utilization safer and more effective is a core component of our business and is increasingly critical as prescription drug utilization and costs continue to rise. AdvancePCS believes that the pragmatic development and implementation of a bar code labeling requirement for human drug products is consistent with our mission to improve prescription drug safety and affordability.

However, AdvancePCS is strongly concerned with the FDA's expressed intent regarding changes to the existing NDC system. The current NDC numbering system is imbedded into virtually all of our systems and processes that deliver prescription benefit management services and in our relationships with health plans, pharmacies and drug manufacturers. Any change to the existing system could potentially be very costly and disruptive -- ultimately raising the cost of prescription drugs and could affect patient safety. Examples of how we use the current numbering system include:

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- **Prescription claim processing.** Prescription claims are submitted electronically to AdvancePCS by pharmacies across the country. These claims are evaluated and disposed electronically based on administrative, financial and clinical criteria. The prescription drug is described in these claims by the NDC number and is used to determine patient co-pay and pharmacy reimbursement, and to test for potential clinical issues such as inappropriate dosing or drug-drug interactions.
- **Formulary management.** Formularies and list of preferred prescription products are an essential tool for health plans to manage cost and quality of prescription drug benefits. A key element of formulary management is the ability to manage products in groups, at different levels. The current NDC system supports this by allowing us to tailor coverage plan design rules, such as whether a drug is covered or not covered, or to designate a particular co-pay tier by product at the package-size level or more broadly to the specific product without consideration of package size.
- **Patient Claim History.** Prescription claim history is defined for our members by NDC number. This history is used to support all of our clinical management programs such as drug utilization review and, disease and case management.
- **Negotiation and management of manufacturer discounts.** AdvancePCS negotiates for prescription drug discounts, in the form of rebates, on behalf of its clients and then administers the billing and collection of agreed-to rebates. The current NDC system supports this process by allowing us to sort prescription drug claims by manufacturer and by product.

In conclusion, AdvancePCS supports the FDA's efforts to develop and implement regulations requiring automated drug identification to improve patient safety, and we believe this effort is an important step towards reducing medication-related errors. However changes to the NDC system could be very disruptive to prescription drug benefit delivery, increasing prescription drug costs and disruption prescription drug safety systems in the face of current rising prescription drug cost and safety concerns.

Thank you again for this opportunity to provide these comments. We would like to meet with you to discuss concerns about the existing NDC system. I will be in touch to schedule this meeting. If you have any questions, please do not hesitate to contact me at (202) 962 3931.

Sincerely,



Susan de Mars
Senior Vice President and General Counsel