Advisory Committee for Pharmaceutical Science Meeting
October 21 - 22, 2003

Topic: Nomenclature
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Nomenclature - Issues and Challenges

Pharmaceutical nomenclature must serve the needs of the scientific, regulatory, public health, legal and marketing communities. Developing nomenclature is a complicated process that engages many governmental, private and public enterprises. The coordination of the efforts by these many communities and organizations is not systematic. It is a real challenge for companies engaged in finding new technologies for the delivery of drugs to also find an acceptable nomenclature for their new product. From the Agency perspective, we face several challenges in the development of science-based legal terminology. The refinement of older terms of art used for centuries by the pharmaceutical industry with newer standards-based definitions is a major issue. Another is the replacement of older dosage forms by newer technologies that have no precedents. Also, the Agency must be aware of bothersome advantage an innovator may inadvertently gain by an overly restrictive definition that allows a virtual monopoly on a particular dosage form. The Agency is also responsible for items in the cosmetic and over-the counter industries, which have different issues requiring another level of oversight. Furthermore, the Agency is interested in harmonizing nomenclature practices to be used throughout the world. Given these challenges, it is imperative that clear and concise names be developed to promote accurate recognition and improve medical communication for a safer health care system.

Committee Discussion

1. How can the Agency best implement new nomenclature or change existing nomenclature to comply with newer standards?
2. Is it reasonable or useful to include a quantifiable attribute when defining a dosage form or distinguishing between closely related dosage forms where appropriate? Can such an approach be viewed as too arbitrary in some cases and too rigid in other cases?

3. Has the update on topical dosage forms presented today addressed the questions/comments raised by the ACPS at the March 2003 meeting?

4. Is the proposed criterion, i.e., USP disintegration time of less than one minute, reasonable for defining an orally disintegrating tablet?