

Department of Health and Human Services, Food and Drug Administration

Docket Number 2006N-0067

Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (Proposed Rule)

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Date of comments: 21 November 2006

Comments:

1. Generally, the proposed rule is quite acceptable, and should provide a much needed alternative to standard NADA requirements, which are least applicable to minor species.
2. The FDA/CVM is to be complimented on their realistic and honest approach to finding safe solutions to correcting the paucity of approved and legally marketable drugs for minor species.
3. Somewhere within the Supplementary Information section of the Proposed Rule there should be a clear statement to the effect that Index Drugs may fall into any of the following categories: over-the-counter, prescription (non-feed based) and Veterinary Feed Directive (feed based). This information was only implicitly provided, and should be explicitly stated.
4. Although possibly implied in several places within the Federal Register Notice, there should be a clear statement that once a drug is placed in the Index by FDA, that the only source from which to legally purchase that index drug is from the Holder (or Holders – see below item #5) identified on the Index.
5. On a related note, the Proposed Rule is not clear on whether or not there can be more than one Holder listed on the Index for any given drug in a particular dosage form and for a particular intended use; i.e., it is presumed, but not stated that a holder of a particular drug/dosage form/intended use combination does not have any marketing exclusivity, which would prevent another prospective holder from seeking index status for their same product.
6. Referencing the Federal Register Notice, page 48856, §516.125(d) – does this paragraph mean that any Target Animal Safety (TAS) studies done under an Index INAD, unlike that of TAS studies to be used for an NADA, are not required to be done under GLP?
7. Referencing the Federal Register Notice, page 48858, §516.141(b)(1) and (c)(1)(iv) – we would recommend that the statement should be changed from “...*must be an expert qualified by training and experience to evaluate the target animal safety and effectiveness...*” to “...*must be an expert qualified by training and experience to evaluate the target animal safety **and/or** effectiveness...*” It may be very difficult to get a panel member to be qualified in both areas, and as long as the composition of the Expert Panel provides for adequate coverage of both study areas, this should be sufficient.