Regulatory Approach to Nanotechnology-Based Drugs For Animals

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Introduction

Outline of presentation
- Brief overview of CVM
- Definition
- Nanoscale materials and the animal drug approval process
The Center for Veterinary Medicine is one of six centers in the FDA which is part of the Department of Health and Human Services

CBER - Center for Biologics Evaluation & Research
CDER - Center for Drug Evaluation & Research
CFSAN - Center for Food Safety & Applied Nutrition
CDRH - Center for Devices & Radiological Health

CVM - Center for Veterinary Medicine

NCTR - National Center for Toxicological Research
ORA – Office of Regulatory Affairs
THE CVM MISSION

The Center for Veterinary Medicine is a consumer protection organization. We foster public and animal health by approving safe and effective products for animals and by enforcing applicable provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) and other authorities.
What does CVM do?

CVM is responsible for assuring that animal drugs and medicated feeds are safe and effective and that food from treated animals is safe to eat.
Definition

- NNI definition: “Nanotechnology is the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications…”
Two “categories” of Nanoscale products

1. Specific nanostructure maintained for effectiveness
   - Intentionally maintain structure
2. Nanostructure not maintained
   - Aggregates break up/dissolve
   - Smaller size provides improved characteristics but essentially smaller particle size versions of “conventional” drugs

“Category” may affect safety evaluations
Animal Drug Approval Process

- Brief overview of approval process
- Briefly discuss animal feeds
- Highlight where nanoscale materials may impact the process
What does it mean to have an approved animal drug:

– Product is safe and effective for intended use
– The methods, facilities, and controls used for the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality, and purity.

NADA = New Animal Drug Application
Regulatory Approach to Products Containing Nanoscale Materials

- Overall premarket approval process is the same as for a “conventional” drug.
- No new regulations (at least for now)
  - Current regulations allow CVM to consider the potential novel properties of products containing nanoscale materials.
- May issue new guidance as appropriate
Technical sections for an Animal Drug Approval

- Effectiveness
- Target Animal Safety
- Human Food Safety
- Chemistry, Manufacturing, and Controls
- Environmental Assessment
- Labeling
- Freedom of Information Summary
Effectiveness

- Same effectiveness criteria as “conventional” drug: substantial evidence of effectiveness
  - Independent substantiation
  - Inferential value

- This may include laboratory and field studies

- Also use information from effectiveness studies for safety evaluations
Target Animal Safety

- Same overall safety criteria – must show drug safe when used as labeled

- Additional variables/procedures in TAS studies may be necessary for a specific product (based on pilot work, published literature on similar product/nanomaterial).
User Safety

Any unique concerns to humans who administer the product to animals?

– Contact with animal drug product before administration, during administration, and after administration
– Veterinarian, animal owner, and others that may contact treated animal
Human Food Safety

- If drug for food animal, must show when animals or animal products are safe for human consumption
- May require new detection methods for determining tissue residues
  - Validate methods
- Toxicology – need appropriate assays and studies
  - If using different assays, justify the assays
Human Food Safety

- Slaughter Authorizations (pre-approval)
  - Only applies to animals used in studies that will enter the food supply
  - Need to provide information to support a request
  - Authorizations and withdrawal times based on available data
Chemistry, Manufacturing, and Controls

- Ensure the methods, facilities, and controls used for the manufacturing, processing, and packaging of the drug are adequate to preserve its identity, strength, quality, and purity.

- Need to confirm formulation

- May need new methods
  - Validate methods for determining particle attributes in formulation
  - Methods for manufacturing controls
Environmental

- May give more consideration to a product before determining if an EA is necessary or granting categorical exclusion.
- Existing categorical exclusions (from the requirement to prepare an EA) may not apply.
- May need more information in decision process (formulation and particle sizes).
- Existing test methods may need to be altered due to unique properties of some nanomaterials. Contaminants (e.g., solvents) may be more of an issue for some products.
Nanoscale materials for feeds may include animal drugs approved through the NADA process (Type A medicated article) and Food Additive Petitions (FAP).

Similar issues as with drug approval process.

Consider detection methods in feeds

– May need new methods
Summary

Overall premarket approval process is similar to a “conventional” drug, but the use of nanoscale materials in animal drugs does present new issues.

- New methods, validate existing methods
- Methods may be product specific

Current regulations allow CVM to consider the potential novel properties of products containing nanoscale materials.

May issue new guidance as appropriate
Thanks for Listening

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