Registration Production Issues for Antimicrobials

July 21, 1999

Presentation to the Pesticide Program Dialogue Committee

Antimicrobial Registration Program Activities

	FY98 Completions	FY99 Completions (as of 6/30)	FY99 Target	% of FY99 Target
New Chemicals	2	1	1	100%
Old Chemical (Fast Track)	102	143	100	143%
Old Chemical (Non-Fast Track)	70	209	70	298%
Experimental Use Permits[1]	1	0	1	0%
New Uses [2]	18	5	13	38%
Amendments (Fast Track)	702	865	500	173%
Amendments (Non-Fast Track)	79	176	75	234%

[1] Anticipated number of EUP's have not been received

[2] New uses have gone down because of the high number of amendments NFT. Also, AD only has 9 pending new use actions due out this fiscal year, the remainder are due out next fiscal year.

Tolerances [3]	2	0	1	0%
Notifications	450	446	500	93%
Product Reregistration	102	26	75	34%
RED's	0	0	4	0%

Antimicrobial Registration Program Activities (Continued)

- Achieved a 98% reduction of backlog items since creation of the division -- working to achieve and maintain a 100% elimination of backlog
- All FQPA registration deadlines have been and continue to be met
- Rulemaking nearing completion
  - ✓ Procedural Rule 152 has completed OMB review and is awaiting signature from Acting Assistant Administrator Susan Wayland and then must be signed by Administrator Browner.

[3] Anticipated target for Tolerances expected to be met

- Finalized FDA & EPA Jurisdiction

  ✓ Clarification of regulatory responsibility for food contact sanitizers has been finalized and released in the FR (FDA Docket 98N-0867, Oct. 9, 1998).

  ✓ Issued final guidance on liquid chemical sterilants (PR Notice 98-2)
- Issued guidance on registration of Manufacturing Use Products (MUP's)

  ✓ This guidance clarified requirements for registering MUP's with an associated end-use product

- Increasing role in preventing foodborne infections (Working closely with health providers, CDC, FDA and USDA)

- Developing test models to better assess exposure under various scenarios

- In the absence of certain data, EPA is using models such as Swim model and cell migration models to better determine real-life exposure

- Created an outreach team with the AD Ombudsman as Team Leader Lead in requests for information; Coordinates enforcement activities; Reaches out to all stakeholders;

Coordinates with Infection Control Specialists in Medical Facilities; Participates in coordination of education initiatives: NAIN, AD Regulatory Guide, Workshops, etc.

- Created the Efficacy and Science Support Branch, to better focus on cutting edge issues.

Future Challenges

- Efficacy

  ✓ Criteria for New Methods & Modifications

  ✓ Treated Articles

  ✓ Fruit and Vegetable sanitizer washes - An interagency panel has been developed including FDA, CDC, USDA and EPA to review the feasibility of developing appropriate protocols

  ✓ Surrogate HBV Test Protocol - Preparing an FR Notice explaining the process for submitting data using the duck as a surrogate.

! Reregistration

✓ Goal is to have 4 REDs completed by end of this FY

- Leveling the Playing Field

  ✓ New policies and policy changes - Policy changes are aimed at enhancing our regulatory performance and productivity while at the same time realigning the division to address escalating cutting edge issues

  ✓ There is a desire that EPA level the playing field for all registrants at the same time. However, certain instances may require that changes begin with a registration application that we have in-house at the time.

- Terms/Graphic Symbols on the label

  ✓ AD is discouraging the use of certain terms if they are too broad, misleading, or not supported by sound laboratory or field studies.

  ✓ Graphic symbols must be consistent with the product's intended use and not be

misleading. Graphic symbols such as lemons (for lemon scent) are unacceptable. Should the Labeling Team or OPP as a unit be more involved?