

CBER Update: Advertising and Promotional Labeling Branch (APLB)

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Agenda

- Changes within APLB and CBER
- Summary of Work and Enforcement
- Examples of Issues/Problems
- Priorities and Goals for 2004

Changes in APLB

- Staff size dropped from 6 to 4 due to transfer of therapeutic biologics from CBER to CDER
- Two APLB staff relocated to DDMAC in July 2003
- All transferring product files have moved to CDER
- All incoming submissions for transferred products are routed to DDMAC upon receipt

Changes in APLB

- Proprietary name reviews for therapeutic biologics transferred to the CDER Office of Drug Safety
- Follow-up activities on all pending enforcement actions have transferred to DDMAC – APLB assisting as requested

Changes in APLB

- Products have been re-distributed within APLB – each reviewer now has a mix of all products (allergenics, vaccines, blood products, cell and gene therapy, devices)
- Opportunity to increase focus on allergenics, vaccines, blood products, and cell/gene therapy products

APLB Staff

- Glenn Byrd, MBA, RAC - Chief
- Nancy Chamberlin, Pharm.D., R.Ph.
- Maryann Gallagher
- Kathryn Smith
- Yongkai Weng, Ph.D.

Current Work in APLB

- Launch materials
- Accelerated approval materials
- Advisory and surveillance review of direct-to-consumer broadcast and print ads
- Review and act on complaints

Current Work in APLB

- Monitor promotional surveillance materials and internet sites
- Unique to CBER:
 - Proprietary name reviews as consults to each product office
 - Blood donor incentives – proposed programs and complaints

Advisory Comment Requests to APLB

**Block 13 on FDA Form 2253
(bottom right-hand corner)**

13. BIOLOGICAL PRODUCTS: (Check one)

Part I/Draft

Part II/Final

Don't just check the box!! Send a cover letter that clearly communicates your intentions/objectives.

APLB Enforcement 2003

- Untitled Letters – five (5) issued in 2003
- Warning Letters – one (1) issued in 2003
- www.fda.gov/cber/efoi/adpromo.htm

Examples of Problems

- Unsubstantiated comparative safety claims
- Minimization of risks
 - Websites that omit important safety information
 - Safety information inadequate in comparison to presentation of effectiveness information

Examples of Problems

- Overstatement of effectiveness
 - Misleading statements of time, ex: long-term; fast
- Presentation of safety and/or effectiveness data that do not constitute substantial evidence
- Inappropriate and misleading superiority claims
- Presentation of unapproved indication for use

Priorities and Goals for Future

- Internally:
 - Decrease review times on all submissions
 - Continue to improve our communications and interactions
- Externally:
 - Continue to work interactively with industry
 - Issue new DTC Brief Summary guidance
 - Vigorous enforcement