

studies No. S-825, S-1367, S-1434, S-1473, S-1518, and S-1546, in Comment No. C00039.

21. Studies ST-2280/2376 in Comment No. C00039.

22. "Twenty-Four Hour Enhanced Duration AP Efficacy Evaluation Under Thermal Stress of: A = AP10001 (Currently Marketed Aerosol Antiperspirant With aluminum chlorohydrate) Against B = AP10008, Placebo Aerosol Antiperspirant," Exhibit 6, in Comment No. C00040.

23. "AP Efficacy 24 Hour Absolute Sweat Reduction Study of: AP10001 (Marketed Aerosol Antiperspirant With Aluminum Chlorohydrate)," Exhibit 5, in Comment No. C00040.

24. Summary Minutes of the 18th Meeting of the Advisory Review Panel on OTC Antiperspirant Drug Products, in OTC Vol. 1400FR, February 26 and 27, 1976.

25. OTC Vol. 140059.

26. Comment No. C00039.

27. Transcript of the 27th Meeting of the Advisory Review Panel on OTC Antiperspirant Drug Products, pp. 75-85, included in OTC Vol. 1400FM, January 26, 1978.

28. Lansdown, A. B. G., "Production of Epidermal Damage in Mammalian Skins by Some Simple Aluminum Compounds," *British Journal of Dermatology*, 89:67-76, 1973.

29. Govett, T., and M. G. DeNavarre, "Aluminum Chlorohydrate, New Antiperspirant Ingredient," *The American Perfumer and Essential Oil Review*, 49:365-368, 1947.

30. "Zirconyl Hy+droxy Chloride Antiperspirant Combinations," Patent No. 2,854,382, U.S. Patent Office, included in Appendix B in OTC Vol. 140037, September 30, 1958.

31. "Characterization of Category I Aluminum Chlorhydrates and Comparison to an Aluminum Chlorhydrate Prepared With an Alternate Neutralization Agent," report in Comment No. C00038.

32. Fifth Supplement, USP 23-NF 18, U.S. Pharmacopeial Convention, Inc., Rockville, MD, p. 3363, 1996.

33. Perl, D. P., and P. F. Good, "Uptake of Aluminum into Central Nervous System Along Nasal-Olfactory Pathways," *Lancet*, 1:1028, May 2, 1987.

34. Inhalation Toxicology Research Institute, Lovelace Biomedical and Environmental Research Institute, "Inhalation Toxicology Studies of Aerosolized Products, Final Report," in Comment SUP.

35. Becton, Dickinson Research Center, "Final Report on Aluminum Chlorhydrate Study," in Comment SUP.

36. Rollin, H. B., P. Theodorou, and T. A. Kilroe-Smith, "Deposition of Aluminum in Tissues of Rabbits Exposed to Inhalation of Low Concentrations of A1203 Dust," *British Journal of Industrial Medicine*, 48:389-391, 1991.

37. Graves, A. B. et al., "The Association Between Aluminum-Containing Products and Alzheimer's Disease," *Journal of Clinical Epidemiology*, 43:35-44, 1990.

38. Garruto, R. M., "Pacific Paradigms of Environmentally Induce Neurological

Disorders: Clinical, Epidemiological and Molecular Perspectives," *Neurotoxicology*, 12:347-377, 1991.

39. Priest, N. D., Satellite Symposium on 'Alzheimer's Disease and Dietary Aluminum', "The Bioavailability and Metabolism of Aluminum Compounds in Man," *Proceedings of the Nutrition Society*, 52:231-240, 1993.

40. Rowan, M. J., "Recent Research on the Causes of Alzheimer's Disease," *Proceedings of the Nutrition Society*, 52:255-262, 1993.

41. Savory, J. et al., "Can the Controversy of the Role of Aluminum in Alzheimer's Disease be Resolved? What are the Suggested Approaches to This Controversy and Methodological Issues to be Considered?," *Journal of Toxicology and Environmental Health*, 48:615-635, 1996.

42. Scott, C. W. et al., "Aggregation of Tau Protein by Aluminum," *Brain Research*, 628:77-84, 1993.

43. Kasa, P., P. Szerdahelyi, and H. M. Wisniewski, "Lack of Topographical Relationship Between Sites of Aluminum Deposition and Senile Plaques in the Alzheimer's Disease Brain," *Acta Neuropathologica*, 90:526-531, 1995.

44. Candy, J. M. et al., "Aluminum Accumulation in Relation to Senile Plaque and Neurofibrillary Tangle Formation in the Brains of Patients With Renal Failure," *Journal of the Neurological Sciences*, 107:210-218, 1992.

45. Anane, R. et al., "Bioaccumulation of Water Soluble Aluminum Chloride in the Hippocampus After Transdermal Uptake in Mice," *Archives of Toxicology*, 69:568-571, 1995.

46. Forbes, W. F., and N. Agwani, "A Suggested Mechanism for Aluminum Biotoxicity," *Journal of Theoretical Biology*, 171:207-214, 1994.

47. Salib, E., and V. Hillier, "A Case-Control Study of Alzheimer's Disease and Aluminum Occupation," *British Journal of Psychiatry*, 168:244-249, 1996.

48. Doll, R., "Review: Alzheimer's Disease and Environmental Aluminum," *Age and Ageing*, 22:138-153, 1993.

49. Flaten, T. P. et al., "Status and Future Concerns of Clinical and Environmental Aluminum Toxicology," *Journal of Toxicology and Environmental Health*, 48:527-541, 1996.

50. Comments No. C46, RPT2, and RPT3.

## List of Subjects

### 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

### 21 CFR Part 350

Labeling, Over-the-counter drugs.

### 21 CFR Part 369

Labeling, Medical devices, Over-the-counter drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner

of Food and Drugs, 21 CFR Chapter I is amended as follows:

## PART 310—NEW DRUGS

■ 1. The authority citation for 21 CFR part 310 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

■ 2. Section 310.545 is amended by redesignating the text of paragraph (a)(4) as paragraph (a)(4)(i), by adding new paragraph (a)(4)(i) heading and paragraphs (a)(4)(ii) and (d)(34), and by revising paragraph (d)(1) to read as follows:

**§ 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.**

(a) \* \* \*

(4) \* \* \*

(i) *Ingredients—Approved as of May 7, 1991.* \* \* \*

(ii) *Approved as of December 9, 2004; June 9, 2005, for products with annual sales less than \$25,000.*

Aluminum sulfate buffered with sodium aluminum lactate

\* \* \* \* \*

(d) \* \* \*

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3)(i), (a)(4)(i), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(10)(i) through (a)(10)(iii), (a)(12)(i) through (a)(12)(iv)(A), (a)(14) through (a)(15)(i), (a)(16) through (a)(18)(i)(A), (a)(18)(ii) (except as covered by paragraph (d)(22) of this section), (a)(18)(iii), (a)(18)(iv), (a)(18)(v)(A), and (a)(18)(vi)(A) of this section.

\* \* \* \* \*

(34) December 9, 2004, for products subject to paragraph (a)(4)(ii) of this section. June 9, 2005, for products with annual sales less than \$25,000.

\* \* \* \* \*

■ 3. Part 350 is added to read as follows:

## PART 350—ANTIPERSPIRANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

### Subpart A—General Provisions

Sec.

350.1 Scope.

350.3 Definition.

### Subpart B—Active Ingredients

350.10 Antiperspirant active ingredients.

### Subpart C—Labeling

350.50 Labeling of antiperspirant drug products.