

## Status of Regulatory Compliance

**American Biaxis Inc.** hereby guarantees that its products, identified as **BIAXIS films**, when used in its unaltered state and in accordance with good manufacturing practices, comply with the following regulations applying to the manufacture of articles intended for contact with food or medical devices:

**BIAXIS film (biaxially oriented nylon 6 film)**

**BIAXIS-HS (High Shrink biaxially oriented nylon 6 film)**

**BIAXIS-RT (Retort Grade biaxially oriented nylon 6 film)**

- FDA Regulation 21 CFR, Part 177, Subpart B, Paragraph 177.1500 (b) 6.1
- Good Manufacturing Practices 21CFR 174.5

**BIAXIS-CT film (Chemically Treated biaxially oriented nylon 6 film)**

When the Chemically Treated side of the film is separated from the food product by a 25 µm (1 mil) polyethylene barrier or the like:

- FDA Regulation 21 CFR 177.1395 "Laminate structures for use at temperatures between 49°C and 121°C (120°F and 250°F)."
- Condition of use B (boiling water sterilized) for food type III (aqueous, acid or nonacid product containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content), or less severe food types, from FDA Regulation 21 CFR 176.170 Tables 1 and 2

Winnipeg, October 14, 2008

**AMERICAN BIAXIS INC.**



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