SÜD-CHEMIE
Creating Performance Technology

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TO: Dockets Management Branch (HFA-305)
Food and Drug Administration
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Rockville, MD 20852.

FROM: Süd-Chemie Performance Packaging
Attn: Mark Florez, Marketing Manager
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Albuquerque, NM 87106
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Comments from Süd-Chemie Performance Packaging (BELEN, NM), a division of Süd-Chemie, Inc. (LOUISVILLE, KY) in regard to the U.S. Food & Drug Administration's Proposed Rules on the Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements

Süd-Chemie Performance Packaging's mission is to create systems and solutions that create a safe environment for our customers' products. Süd-Chemie is a manufacturer and supplier of desiccants, absorbents, humidity indicators, and polymer packaging solutions. The company is a key supplier to the pharmaceutical, diagnostic and nutritional industries for desiccant canisters, desiccant packets, desiccant bags for bulk packaging, polymer-based tubes and desiccant stoppers, and customized packaging and dispensing solutions. Süd-Chemie supplies virtually all major pharmaceutical manufacturers and several major diagnostic and nutritional manufacturers with its products.

Our vast experience in providing desiccant and packaging components to the pharmaceutical industry gives us insight into the need for sound practices and requirements for packaging medicinal products intended for the health of the public. The following statement is meant to comment and educate on the types of products that could be used to accomplish some of the goals outlined in the proposed rules entered into the Federal Register March 13, 2003 (Volume 68, Number 49). Süd-Chemie supports the measures being taken by the FDA to increase the level of confidence in consumers that nutritional and dietary supplements meet sound, necessary regulations for safety and product integrity.

Desiccants

Simply stated, a desiccant is a drying agent used to combat humidity or moisture degradation. For pharmaceuticals, diagnostic, and nutritional products, a desiccant is required to (1) maintain the integrity of a tablet or capsule (avoid clumping or sticking), (2) avoid undesired chemical reactions with ambient moisture inside packaging, (3) increase shelf-life by inhibiting moisture degradation of products, (4) control any unwanted microbial activity that thrives in moist environments, and/or (5) Absorb other particles that cause other problems, such as odor, by integrating a carbon getter.

95N-0304 C4023

Desiccants address the humidity issue stated in Section 111.80 that states:

> (a) You must hold components, dietary ingredients, and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, purity, quality, strength, and composition of the components, dietary ingredients, and dietary supplements are not affected.
>
> (b) You must hold packaging and labels under appropriate conditions of temperature, humidity, and light so that the quality of the packaging and labels are not affected.

Desiccants from Süd-Chemie are considered Generally Recognized As Safe (GRAS) materials as stated by Title 21 of the Code of Federal Regulations. All Süd-Chemie desiccants and manufacturing practices and facilities are compliant with FDA and US Pharmacoepia (USP) standards.

Desiccant Canisters
(Photos 1 & 2)

Desiccant Canisters are considered the gold standard among the desiccants used in the pharmaceutical industry. In addition to being able to contain between 0.5 grams and 3 grams of desiccant, canisters are specifically designed for high-speed product insertion and have less potential for contamination and machine jamming than desiccant packets. Desiccant Canisters are also widely used by the nutritional industry.

Desiccant Packets
(Photos 2 & 3)

Desiccant packets are available as either individual packets or long strips that are cut into separate packets upon being inserted into a package. Packets have fill weights that contain between 0.25 grams and 10 grams of desiccant. Various facestock materials are used to manufacture packets, including Dupont Tyvek® (spunbonded polyolefin), which address non-dusting issues that are covered by industry standards and regulations.

Cap Inserts
(Photo 4)

Desiccant cap inserts are used in conjunction with screw-on caps for rigid containers. The desiccant is contained in the cap insert. Since desiccant-filled inserts fit directly into the cap, the desiccant does not take up any extra space in the container itself.

Tube and Stopper Systems
(Photos 5 & 6)

The tube and desiccant stopper system is the one of the most advanced moisture-protection packaging for nutritional and dietary supplements. Similar to the cap insert, the desiccant is contained in the stopper, does not consume any extra space in the tube, and requires no additional desiccant feeding system. The desiccation and protection functions of the stopper can also be combined with such safety features as child resistance and tamper evidence. Stoppers designed for packaging of effervescent

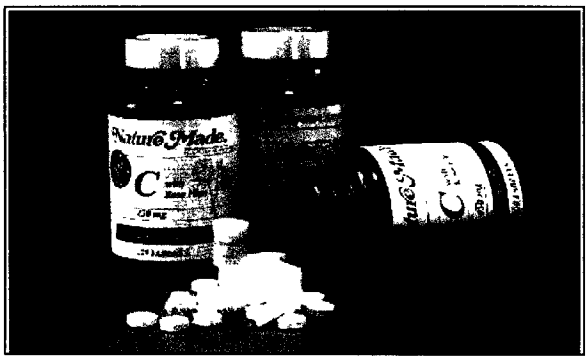
tablets include a spiral that holds tablets in place, maintaining integrity and eliminating the need for cotton fill.

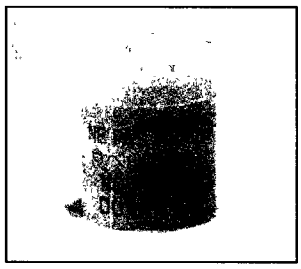
Desiccant-Filled Polymers

Another moisture-protection option is to incorporate a desiccant into the polymer material that is used in tubes for strip storage and housings for test kits. These tubes and devices consist of an outer layer of moisture-impermeable material and an inner layer of desiccant-filled polymer material. Absorption capacity and rate can be adjusted by choosing certain plastic materials, desiccant types, desiccant amounts, and additives.

Desiccant Types and Performance

Three types of desiccants are currently used for moisture protection in pharmaceuticals, diagnostic, and nutritional products: silica gel, molecular sieves, and desiccant clay. Among these, silica gel is the most widely used for pharmaceutical, diagnostic, and nutritional applications. All three have properties that can stabilize and preserve nutritional and dietary products as directed by the proposed rules. Desiccant clay, a bentonite clay, is often a logical solution for nutritionals because (1) it absorption capacity is higher than silica gel at low humidities, (2) it is an natural inorganic substance (not synthetic), (3) it is less expensive than the other two desiccants, and (4) also complies with FDA and USP regulations.





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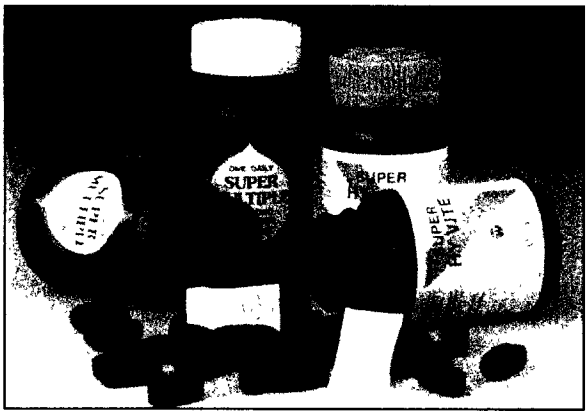

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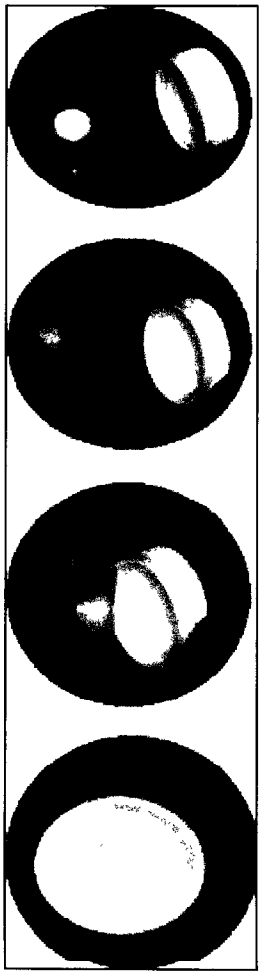

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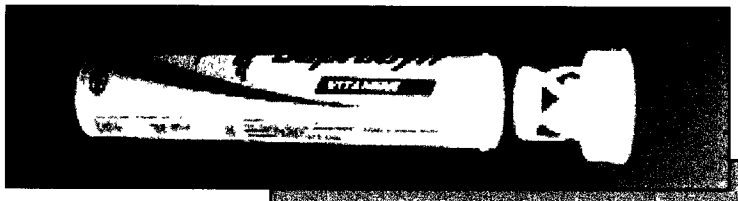

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