Oat Beta-Glucan: Source and Manufacturing Process

The oat beta-glucan that is the subject of this petition (PromOat® Beta Glucan) is a fraction of milled whole oat grain, derived from the bran, which is gently processed using physical separation and an alpha-amylase enzyme in downstream processing. The end product is rich in the soluble fiber component, beta glucan. It is neutral in color and has a clean, mildly oaty flavor and no graininess.

The source material is whole grain oats of the *Avena sativa*, SW Kerstin variety (non-GMO). The oat beta-glucan is extracted from the source whole grain oats by a process involving both dry milling and wet milling. First, in dry milling, the oat kernels are ground and the bran is separated from the rest of the grain. In the wet milling process that follows, water and an alpha amylase enzyme are added to the ground oat bran, along with heat, to enhance the separation of the beta-glucan soluble fiber from the other bran components. This mixture is then physically decanted to remove the soluble substances. The soluble solids that remain are rolled and dried to yield a fine powder that is rich in beta-glucan.

The enzyme used in processing is derived from a non-pathogenic, non-GMO microorganism (*Bacillus licheniformis*). Alpha-amylase from *B. licheniformis* is GRAS for food manufacturing per 21 CFR 184.1027. This enzyme meets the requirements in 7 CFR 205.605a of the National List.

There are no added chemicals in the manufacturing process for this oat beta-glucan, including chemicals used to adjust pH or bleach out the color, and chemical solvents.

The attachment shows the stepwise manufacture of PromOat® Oat Beta Glucan.