The Case for Using the OTC Drug Monograph Structure for Probiotics

1. Well established mechanism with 40 years experience (21 CFR 330 et seq.)
3. Existing office within FDA Center for Drug Evaluation & Research already handles monograph questions (would need new resources)
4. Hammer of Republican House Investigations by D. Issa et al against FDA over-regulation makes it unlikely that FDA will accept any invitations to make new regulatory models or pathways
5. Well understood set of claims, accepted by FTC and useful in private enforcement claims vs bad actors under Lanham Act and state laws
6. Open process leading to final enforceable rule, lots of science input
7. Outlier company/claim proponent has option to seek NDA for claims exceeding these monograph claims
8. Current CFSAN systems are broken, GRAS system virtually abandoned and 1997 proposed rule never made final
9. Strong basis for characterization and production controls on ingredients
10. AND it’s likely to sail through the likely court challenges