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| This checklist should be used to determine exemption of products which have been designated as “Generally Safe” or if the product is a marketed product being used to produce a physiological challenge in the U.S. | | |
| eBridge PRO Number: | Product/Compound Name: | |
| 21 CFR 312.2(b) GRAS Products **To be exempt under this category, these sub-requirements must apply**: | | |
| 1. The product being evaluated is a dietary supplement, botanical, amino acid or other substance designated as generally safe (GRAS) | | Yes |
| 1. Intended use is only to affect the structure or any function of the body | | Yes |
| 1. The product is not intended to be used for a therapeutic purpose (ability to diagnose, cure, mitigate, treat or prevent disease) | | Yes |
| 1. The project does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the product.   Please provide justification: | | Yes |
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| 21 CFR 312.2(b) **The research project/clinical investigation includes use of a marketed product in physiological challenge project. To be exempt under this category, these sub-requirements must apply**: | | |
| 1. The clinical investigation involves a drug product lawfully marketed in the U.S. | | Yes |
| 1. The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use and is not intended to be used to support any other significant change in the labeling for the drug | | Yes |
| 1. If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product | | Yes |
| 1. The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product. If oncologic therapy and IND is not necessary to permit deviations from the approved labeling to the extent that such changes are supported by the scientific literature and generally known clinical experience.   Please provide justification: | | Yes |
| 1. The investigation is conducted in compliance with the requirements for IRB review set forth in21 CFR Part 56 and with the requirements for informed consent set forth in 21 CFR Part 50 | | Yes |