Request for Proposal: IND Regulatory Strategy for Fake Hats Co.

Company Overview

Company Name	Fake Hats Company
CEO	Bob Sacamano
CTO (PI)	Elaine Benes
Company website	www.FakeHats.net
Technology Summary	Small molecule therapeutic (PES-456) is being developed as a first line therapy for Purple Ear Syndrome
Major market(s)	Purple Ear Syndrome patients (400,000 world-wide)
Technology stage	Pre-clinical safety & efficacy with lead compound
Primary regulatory path	Orphan Indication, NDA (New Drug Application)

Context of Service Request:

Fake Hats Co. needs assistance with the development of an initial FDA interaction and submission of a new IND file to support the development of its first therapeutic molecule PES-456. PES-456 is being developed to resolve the symptomology of Purple Ear Syndrome – a condition where excessive blood flow to the tympanic membrane results in a characteristic purple color and which impacts the lives of effected people in one or more of the following ways: difficulty hearing; tinnitus; inability to "clear" ears during changes in altitude (leading to increased potential for ruptured ear drums); and challenges in balance (due to unequal pressure in eustachian tubes). Purple Ear Syndrome is an intermittent condition that can affect one or both ears, individually or simultaneously.

Fake Hat Co. has not had any documented interactions with the US FDA, though we have spoken with FDA representatives at scientific meetings and were guided to several relevant and informative guidance documents. We also met with the regulatory team at NIH to discuss possible pathways and used information from the following documents to guide our manufacturing and early animal studies:

- Current GMP for Phase 1 Investigational Drugs
- ICH Q6A Specifications: Test procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances
- ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
- ICH Q7 QandAs Questions and Answers: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
- ICH S1B-R1 Testing for Carcinogenicity of Pharmaceuticals
- FDA Guidance Rare Diseases Natural History Studies

We are in the final stages of engaging a CRO to conduct our IND enabling P/T studies and anticipate submitting our IND by Q2 next calendar year. We are seeking regulatory support to assist in the development and submission of our IND, including drafting SAD/MAD clinical protocols.

Deliverables and Reporting Requirements:

The expected deliverable is submission of our IND to the appropriate FDA Office and allowance of our clinical trial. Interim milestones to achieve this deliverable might include:

- An analysis of documentation developed by Fake Hats to support the IND submission
- Review of data provided by the CRO performing the IND enabling P/T studies to ensure the data they will provide is sufficient to support the review of the IND file
- Collaborative development of an IND application for PES-456
- Development of an Investigators Brochure to support the Phase 1 trials for PES-456
- Successful submission of the IND for PES-456
- Collaborative development of response to reviewer comments during the IND review cycle

Vendor Qualifications:

- Recent experience (within the past 3 years) working with the relevant FDA review division
- Extensive expertise successfully submitting documents to FDA for small molecules
- Experience submitting INDs for auditory therapeutics