Samples of Comments for FDA Draft Rule

Example of comment addressing one ingredient:

My comment will address the following ingredient(s):

Chondroitin Sulfate

Functional Uses/ Disease Indications:

It is compounded with a product called Low Dose Antigen and used to treat allergies to foods and inhalants as well as treating some autoimmune disorders.

Clinical Experience:

I have used this form of therapy for over a decade with significant benefit to my patients. Their allergies to foods and inhalants improve a minimum of 80% over 90% of the time with very minimal side effects. I have seen no anaphylaxis or exacerbation of dangerous symptoms with this treatment. In fact, every patient that had anaphylaxis who has been treated and then again tried the product in question, has not had a return of their symptoms.

Observed Adverse Effects:

Theoretically there is the possibility of creating an allergic reaction that escalates if the patient does not adhere to the guidelines of therapy. The common reactions are pain, redness and swelling at the site of injection which is given in the forearm.

Advantages Over Approved Pharmaceuticals:

Low Dose Antigen is thought to treat foods and chemicals more permanently through both a neurologic and immunologic pathway which no other approved pharmaceutical does. It treats the illness and not the symptoms as do the pharmaceutical products.

Treatment Gap Created by Loss of Ingredient:

It would be significant and harmful to many patients receiving the therapy as well as preventing physicians from utilizing one of the most beneficial allergy treatments one the planet.

Extent of Historical Use:

Chondroitin Sulfate was used in an allergy treatment called Enzyme Potentiated Desensitization which Low Dose Antigen was fashioned upon when it was no longer available.
Example of comment addressing multiple ingredients:

My comment will address the following ingredient(s):
EGCG, VIP, Crysin

Functional Uses/Disease Indications:

EGCG is compounded into vaginal suppositories for abnormal Pap smears and HPV. VIP is used for patients who have CIRS with mold toxicity and low VIP as laboratory tested. Crysin is used in topical testosterone creams to prevents aromatization.

Clinical Experience:

I have used EGCG for 10 years with great efficacy in conjunction with a full treatment plan. It is well tolerated. Patients will have to make their own at home which is not what I want them to be doing. VIP resolves low energy, anxiety, and constipation in CIRS patients. There is no other way for patients to take this. This is not well tolerated initially and must be increased gradually. Crysin helps with aromatization and is better tolerated that anastrozole. I get better compliance when added to the cream than taken separately. This is very well tolerated.

Observed Adverse Effects:

EGCG: None seen
VIP: Nasal irritation
Crysin: None seen

Advantages Over Approved Pharmaceuticals:

EGCG: No pharmaceuticals available
VIP: No pharmaceuticals available
Crysin: Anastrozole causes joint degradation and pain.

Treatment Gap Created by Loss of Ingredient:

EGCG: HPV and cervical dysplasia, which leaves the only treatment option as LEEP (Loop Electrosurgical Excision Procedure) surgery which can cause an inability to carry a child.

VIP: Patients don't heal as well or it takes a lot longer to heal from fatigue, anxiety and constipation.

Crysin: Patients have to take anastrozole or OTC Crysin. Anastrozole is harmful to joints and OTC Crysin isn't regulated as well as the compounded.