

# Advice to the Lab Lorn

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Susan Raffy Allen and John Garruto

## (Part 2 of a 2-part series)

- 2.** We are given projects by our marketing department and sometimes it is not always clear what is required with respect to product function, ingredients and other key criterion. Sometimes we will work on a project only to find that the lab submission is unacceptable based on factors that were not discussed at the beginning of the project. What can we do to improve the communication between R&D and Marketing to avoid these delays on future projects?

### Conclusion:

#### Step # 4 - Submit Initial Prototype to Marketing

When the R&D chemist has completed the initial development, such that there is a high degree of confidence that the target has reasonably been met, samples of the prototype can be submitted to marketing for evaluation and comment. This procedure usually involves an in-house review team that evaluates the prototypes for sensory and performance targets as well as for overall adherence to the target as described in the product profile. If the prototype does not meet all of the criteria, R&D personnel will make the necessary modifications and resubmit samples for testing. If the prototype is generally well received, the marketing department may expand the product evaluation to a larger group within the company or to an outside panel of product evaluators or a focus group. This evaluation will continue until the marketing department has approved the product. When the product has been approved, it is always a good idea to once again calculate and restate the raw material cost of the formula. If the R&D staff has followed the required costing parameters, there should not be a problem. Assuming all is well, product testing will be initiated.

#### Step # 5 - Product Testing

Once the prototype has been approved, the development phase of the project gives way to product testing. This usually involves a combination of in-house and off site testing. This should include stability testing of the product in laboratory glass as well as final product packaging. The physical stability testing will most often be carried out for a minimum of ninety days and will usually include low temperature, room temperature, and elevated temperature analysis as well as freeze/thaw cycle testing. Many established criteria are evaluated and usually include parameters of appearance, color, odor, pH, viscosity, specific gravity and percent solids/weight loss. These criteria may also include testing for active substances if the product is considered an over the counter drug (OTC), such as a sunscreen, antiperspirant, acne preparation, etc. Additionally a Preservative Effectiveness Test (PET) is performed by USP, CTFA or similar protocol. There may also be performance claims made for the product, either on the package or in product advertising that will need to be substantiated, usually with an in-house or independent testing laboratory. When there is confidence that all stability/efficacy testing is well in hand and that no further formula modifications are likely, safety testing should commence. This may include Repeat Insult Patch Testing (RIPT), a controlled use study and possibly an in-vitro protocol for eye irritation or other criteria. When all testing is complete and acceptable to all departments, the formula receives final approval and the scale-up process can proceed. At this point all product copy including ingredients, claims, fill capacity, directions and label warnings, if needed, should have been reviewed and approved.

(cont'd on pg. 12)

in-no-vate (in'əvāt') -v.i.  
1. the act of formulating with unique Lipo ingredients and technologies.




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## Advice to the Lab Lorn

(cont'd from pg. 3)

### Step # 6 – Scale-up/Manufacturing

When the final approval is given, the scale-up process can begin. A copy of the product formula and complete bill of materials is given to the manufacturing department or contract manufacturer. The formula will be used to develop manufacturing batch documents that will detail the qualitative and quantitative aspects of all raw materials in the product, as well as the required manufacturing equipment, batching procedure, and other relevant information necessary to successfully manufacture the product. This will also include any relevant processing conditions with respect to temperature, mixing speed and any filling protocol, including fill capacity, labeling, cap torque and batch coding requirements. The complete product specifications and quality testing parameters should also be detailed as well as a description of the product release procedure. If the product is to be manufactured off-site, at a contract manufacturing facility, a lab batch should be made by the contract manufacturer and approved. At this point, a pilot batch is usually manufactured in order to work out the details of the manufacturing process in a real world environment. All information relevant to manufacturing equipment and procedures should be documented, updated and kept with the master batch record. Once the pilot batch is successfully manufactured, tested and released, a full size production batch is scheduled. In the case of small production requirements, the pilot batch will serve as the full manufacturing requirement. When the product is released, it is ready to ship and be distributed to the marketplace.

### Step # 7 – Sales

The most notable achievement of a product launch is certainly embodied in the fulfillment of sales goals and commercial success. While there is no guarantee of this outcome in a fiercely competitive environment, we can certainly tilt the scale in our favor with careful planning and exceptional teamwork. This often means that each step in the process is detailed with a critical path of our own design and agreement. It is vital that we move through the product development process, in a well-planned, systematic manner, while continuing to maintain a dialog with all parties involved. Nothing should be left to chance and there should always be sufficient time built into the schedule to allow for the invariable contingency that will often occur at exactly the wrong time. There is an ancient African proverb that states that we should "never test the depth of the river with both feet". Be prepared, be organized, be cooperative and you will be successful.

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