Engineering World Health Liquid Medication Delivery System 10/01/2008

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Product Design Specifications

Function: This device will be used for two purposes: to seal bottles of medications donated to pharmacies in developing countries and allow the pharmacy technicians to dispense the proper dosage while keeping the medication free from spoilage and contamination.

1. Physical and Operational Characteristics

- a. *Performance requirements*: The device must function properly for at least 4000 doses. The device must allow the user to dispense individual doses. The bottle must remain sealed while not in use.
- b. *Safety*: No labeling or safety warnings are needed on the device because it will be included on the bottle. A manual with simple instructions will be included. The device should be shatter-proof and able to withstand dropping from 2 meters.
- c. *Accuracy and Reliability*: The device must dispense 0.6mL of medication. Each dose dispensed must be within 0.05mL of the targeted dose.
- d. *Life in Service*: The minimum life in service is 6 months, which is how long a bottle of medication can be open before it must be discarded. No maintenance should be required for the device. Most importantly, the device must function properly for at least 4000 doses, which would accommodate the maximum number of doses in a container.
- e. *Shelf Life*: The device must last at least 5 years on the shelf. It must be able to survive an overseas shipment (~16 hours at conditions varying between -10°C-40°C shipping and subject to various pressures).
- f. Operating Environment: The storage environment and operating environment have the same conditions. The device will be on a pharmacy shelf, which has a temperature range of -5°C to 40°C and standard atmospheric pressure. Dirt and dust may be abundant in the environment, so the device should keep these and other contaminants (including insects) out. The device should not be corroded by either the medication or by ambient humidity. The device will only be handled by trained pharmacy technicians.

- g. *Ergonomics*: The loading patterns depend on the design chosen, but the device will be designed based on anthropometric data such that 99% of the population can exert the force required to use the device.
- h. *Size*: The device must fit into or around the mouth of the plastic medication bottles. The device will be designed to fit into plastic bottles that the group can obtain that are of the appropriate volumes, with the understanding that the design dimensions can be adapted to fit on the bottles Boehringer Ingelheim uses for their medication.
- i. Weight: The weight should be kept to a minimum without sacrificing design.
- j. *Materials*: Any material can be used provided it allows the design to remain in the cost target area and won't react with the medication or corrode over time.

2. Production Characteristics

- a. Quantity: Should be produced in quantities of 2000.
- b. *Target Product Cost*: Our group has set a goal of \$0.50 based on conversations with Robert Malkin, but the published maximum is \$2 each when produced at volumes of 2000.

3. Miscellaneous

- a. *Patient-related concerns*: Engineering World Health will own all rights of the project once we submit the idea and receive funding. The design will be placed in the public domain at this time.
- b. *Competition*: Similar items exist but are too expensive for use in developing countries.