Before-Use Admixture of Components Stored in a Two-Chamber Container: Possible Medical and Nutritional Applications of the Recotec Technology

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Many pharmaceuticals and nutritional products are manufactured in the form of a powder. These powders need to be suspended or dissolved in an appropriate liquid before use. Storing these products as powders has many advantages, among them a prolonged shelf life, reduced volume and weight, and conditions unsuitable for bacterial growth. However, the current methods of reconstitution of these products require time and have the potential disadvantages of mistakes in proportions, introduction of unwanted pollutants or germs, etc.

M.L.I.S. Projects Ltd. has devised a new patented technology aimed at providing a packaging system in which both the powder and its complementary liquid are stored in separate compartments of the same device. The bottle contains an internal mechanism that is responsible for keeping the different compartments separate. This mechanism is connected to an external operating ring, which after a simple twist activates the container, i.e., opens the internal septum allowing mixing of the two components.

There are many applications for this packaging system. With regard to medicine, they range from children's antibiotics to hormones, blood products and chemotherapy drugs. For nutrition, the applications may be baby formulas, enteral feeding, nutritional supplements, etc.

The container can be produced with two separate compartments, or more. The compartments are filled with appropriate powders or liquids. An existing application of this core technology is the Twist 'N Feed baby bottle [Figures 1 and 2] [1–4]. This bottle is produced using appropriate molds for injection of polypropylene plastic parts, which are then assembled in the form of a disposable baby feeding bottle. This bottle is filled through two different openings – baby formula in one compartment and purified sterilized water in the other, in accurate amounts to form the appropriate ratio. Upon activation of the bottle, the formula is ready to use. The Twist 'N Feed baby bottle carries a number of advantages over the two existing methods of formula preparation in hospitals. Compared to reconstituted powder formulas, it allows a sterile mixing process, prevents mixing mistakes and is economical in terms of time and manpower spared. When compared to ready-to-use liquid preparations, it has the advantage of a longer shelf life and the absence of additives, stabilizing agents, emulsifiers etc. It also precludes a costly sterilization process.

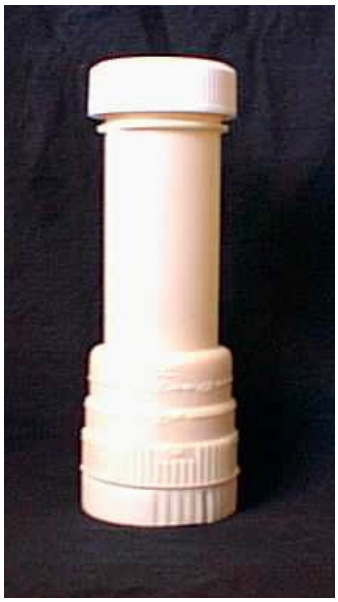

Figure 1. Before activation.

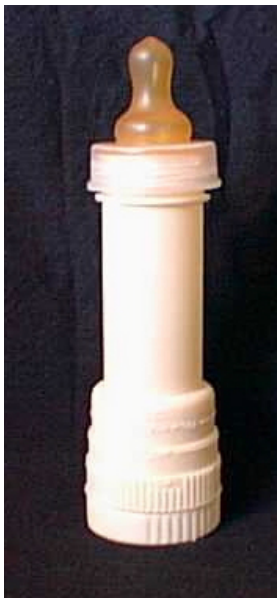

Figure 2. Ready for feeding.

To date, more than 7,000 Twist 'N Feed bottles have been tested in five different medical centers in Israel and were found suitable for all baby powders manufactured worldwide. At present, additional clinical studies are in progress.

The information from the clinical trials has been used to produce the

current baby bottle for hospital use. This bottle is designed for feeding of newborn babies. In addition, field trials have been initiated to test its acceptance by parents after their discharge from the hospital with their babies. Clinical trials are being designed for use of the above technology in other medical applications.

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Capsule

Fetal immunization by DNA

Infectious diseases are the main cause of neonatal morbidity and mortality in humans. The World Health Organization estimated that in 1995 approximately 8 million infants died within the first year of life from infectious diseases, including 5 million during the first week of life. Some of the salient pathogens involved include herpes simplex virus, human immunodeficiency virus, hepatitis B virus, human cytomegalovirus, group B *Streptococcus*, and *Chlamydia*. Infection with these pathogens usually occurs at the end of pregnancy, during birth or by breast-feeding. To reduce the risk of disease transmission, cesarian sections, prophylactic treatment with antibiotics, or maternal antiviral therapy during the last trimester are used where available, together with improved neonatal care. None of these approaches, however, completely eliminates the risk of neonatal infection. Therefore, active or passive immunization of the fetus might represent an effective approach to reduce the high risk of neonatal diseases.

Gredts et al. demonstrate that a single immunization with a DNA vaccine delivered into the amniotic fluid in the oral cavity induces high serum antibody titers and a cell-mediated immune response, combined with induction of local immunity in the oral cavities of fetal lambs.

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I like the evening in India, the one magic moment when the sun balances on the rim of the world, and the hush descends, and ten thousand civil servants drift homeward on a river of bicycles, brooding on the Lord Krishna and the cost of living.

James Cameron, Scottish journalist (1911–85)

Capsule

Adverse drug reactions

The numbers of deaths attributed to adverse drug reactions by death certificates and by the Food and Drug Administration were compared by Chyka in order to characterize national mortality statistics.

Results showed that 206 deaths during 1995 were attributed to adverse drug reactions on death certificates in the United States, whereas MedWatch tabulated 6,894 fatalities. The proportions of men and women were similar, and the majority of deaths involved persons 60 years of age and older, in both data sets. The rankings of drug categories associated with adverse drug reactions differed in the two data sets. The author concludes that the numbers of deaths reported in these data sets varied 34-fold and were up to several 100-fold less than values based on extrapolations of surveillance programs. These differences indicate that better and more comprehensive data are needed to develop appropriate health care policies to improve drug safety.

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