



# ***PHELON PARTS, INC.***

P.O. BOX 2804 - Santa Isabel, PR 00757-2804 - TEL.: (787) 845-5100

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## **CITIZEN PETITION**

The undersigned submits this petition pursuant to the provisions of 21 CFR Part 10 of the Federal Food, Drug and Cosmetic Act to request the Commissioner of the Food and Drug Administration to issue an order authorizing PHELON PARTS, INC. to purchase and use nitrous oxide gas as part of the manufacturing process of the Phelon Group.

### **A. Action Requested**

It is hereby requested that the Commissioner of the Food and Drug Administration issue an order authorizing PHELON PARTS, INC. to purchase and use nitrous oxide gas as part of the manufacturing process of the Phelon Group.

### **B. Statement of Grounds**

Phelon Parts, Inc. is part of the Phelon Group, which includes Power Parts, Inc. and RE Phelon Co., involved for over 50 years in the manufacturing of innovative ignition systems for everything from garden tractors to weed trimmers, and manages world class manufacturing facilities in the Dominican Republic. As part of the manufacturing process of our products, nitrous oxide has been used for over 18 years with an annual consumption of approximately 230 cylinders of the gas used to break surface tension of polypropylene cups and ease the adhesion of epoxy to encapsulate our product.

### **C. Environmental Impact**

There will be no environmental impact as a result of the requested action. As before stated, nitrous oxide gas has been used for over 18 years as part of the manufacturing process of our products, without any environmental impact resulting therefrom.

2005P-0035

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D. Certification

IT IS CERTIFIED, that to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and there includes representative data and information known to the petitioner which are unfavorable to the Petition.

In Santa Isabel, Puerto Rico, this 8th of November, 2004.

**PHELON PARTS, INC.**  
Petitioner

Box 2804  
Santa Isabel, PR 00757  
Tel. 787-845-5100

By:



**J. EVERETT MILOTT**  
Executive Vice President  
and General Manager