DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
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NIOSH Reference: TN-17561
Mfr. Reference: CHPF550Ca

March 2, 2011

Ms. Natalie Lin
Champak Enterprise Co., Ltd.
No.27-1, Jhaiming Street
Dasi Township
Taoyuan County, 33561
Taiwan

Dear Ms. Lin:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted January 5, 2011. This request was for an extension of approval to TC-84A-4394 to add a new model N95 filtering facepiece air purifying respirator with a head strap adjustment buckle under the model number F550C, reference assembly matrix CHPF550AMb.xls. In addition, this request included the addition of a private label version to Pasture Pharma Pte, Ltd., of Singapore under the model number PastureF550C.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English.

The CD enclosed with this letter contains the final respirator approval labels. The abbreviated labels have been accepted as submitted. The cautions and limitations which apply to this approval are on the approval labels. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assemblies consist of the parts as listed on the approval labels and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

The manufacturer is responsible for properly packaging, labeling, and controlling the respirators produced under this private label approval. At a minimum, the items that must be controlled are the approved user instructions, all approval labeling, all approved packaging, use claims, marketing materials, and the respirator designs and construction details. Any changes to this NIOSH-approved respirator or to the approval documentation without prior notification and approval are a violation of this approval and renders this certification as invalid.

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely yours,

Heinz W. Ahlers
Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures