PRODUCT PERFORMANCE / EFFICACY REVIEW
Mark Suarez, Entomologist - IB

DATE:	1 May 2009
EPA REG. NUMBER:	82392-1
PRODUCT NAME:	Perimeter Insect Guard Insect Repellent Apparel
REGISTRANT:	Pinebelt Processing, Inc.
PM:	PM 13
REVIEWER:	Lind DeLuise
DECISION #.:	404115
DP BARCODE:	360410
ACTION:	R340
ACTIVE INGREDIENT(S):	109701, Permethrin.....0.52%
TYPE:	Fabric Treatment
OPPTS GUIDELINE(S):	810.3300, as applicable
MRID:	47634401 Submitted GLP? No.
SITES & PESTS	Fabric Treatment Mosquitoes, Sand flies
STUDY APPLICATION RATE:	N/A
LABEL APPLICATION RATE:	N/A

STUDY SUMMARIES:

MRID 47634401. Lack, R. (2008) Perimeter Insect Guard Repellent Apparel: Product Performance. Project Number: 82392/1. Unpublished study prepared by US Army Research, Development & Engineering Command. 14 p.

N/A

ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

The data provided in MRID 47634401 could not be evaluated due to the incomplete nature of the study report. The data contained within the study were generated on human subjects. The trial was initiated after April 7, 2006 and is subject to the requirements of 40 CFR §26 – Protection of Human Subjects.

Subpart K of the rule [40 CFR §26.1125] allows agencies that are subject to the provisions of the Federal Policy for the Protection of Human Subjects of Research and any person when performing human research supported by a federal agency, to submit human studies data without prior submission of the protocol for EPA and HSRB review. However, the expectation is the study submitted will be conducted in a manner that is consistent with the scientific and ethical standards applied to other submissions. (It is not clear that this study is exempt from the protocol submission requirement.)

No exclusion from the submission of completed human research generated by common rule agencies to the HSRB exists, per Subpart P of the rule [40 CFR §26.1602]. Therefore, the submitted study must contain all the information required for a full evaluation of the science and ethics.

The submitted study was deemed deficient.

Some of the major deficiencies noted for MRID 47634401 are:

1.) The study report does not provide clear materials and methods or results. The report is written in a proposal format. This does not inform the reviewer of the actual methodologies employed. The raw data were not included in the study report.
2.) The sponsor of the study is not clear. Thus, it is not clear if the study can evaluated without prior protocol submission and review under the allowance for common rule agencies.
3.) The ethical aspects of the study could not be evaluated (see 40 CFR §26).

Enclosure
082392-0001 S841811-ER

3