

Product Name: \_\_\_\_\_

DTN: \_\_\_\_\_

**SELF-ASSESSMENT CHECKLIST FOR OFF-LABEL USE/PUBLIC HEALTH  
EMERGENCY EXEMPTION PERMIT APPLICATION**

DOCUMENTARY REQUIREMENTS	YES	NO	Remarks	FDA's Use Only
<b>1. Application Form/Letter of Request</b>				
<b>2. Information required for public health exemption:</b>				
a. Scientific and common name of the pest to be controlled and, if the pest is a vector, a description of the disease it is expected to transmit				
b. Discussion of the magnitude of health problems expected to occur without the possible use				
c. Discussion of availability of medical treatment for the health problem				
<b>3. Description of the pesticide</b>				
a. Complete ingredient listing of the formulated finished product				
b. Complete labeling to be used in connection with the proposed exemption use				
<b>4. Description of the proposed use</b>				
a. Sites to be treated, including locations within the country				
b. Method of application				
c. Rate of application in terms of active ingredient and product				
d. Maximum number of applications				
e. Total area proposed to be treated				
f. Total amount of product proposed to be used in terms of both active ingredient and product				
g. All applicable restrictions and requirements concerning the proposed use which may not appear on labelling				
h. Duration of the proposed use				
<b>5. Alternative methods of control</b>				
a. Detailed explanation why the household pesticide(s) currently registered for the particular use proposed in the application is not available in adequate supplies and/or effective to the degree needed to control the emergency. If the applicant states that an available registered household pesticide is ineffective for the given situation, the statement must be supported by data which demonstrate ineffectiveness of registered HUPs, or, if such data are unavailable, statements by qualified pesticide experts, academe or other person similarly qualified in the field of pest control				

b. Detailed explanation of why alternative practices, if available, either would not provide adequate control or would not be economically or environmentally feasible				
<b>6. Effectiveness of proposed use (Bio-efficacy Study)</b>				
<b>7. Discussion of risk information (Toxicity Study)</b>				
<b>8. Description of the proposed enforcement program</b>				
a. Explanation of the authority of the applicant for ensuring that use of the household pesticide under the proposed exemption would comply with any special requirements imposed by FDA				
b. Description of the program and procedures for assuring compliance				

--- To be filled out by CCHUHSRR Personnel ---

<b>Evaluator:</b>		<b>Signature:</b>	
<b>Position:</b>		<b>Date:</b>	
<b>Decision:</b>	<input type="checkbox"/> Acceptance <input type="checkbox"/> Non-acceptance	<b>Remarks:</b>	