Littlewing pearlymussel
Pegias fabula

5-Year Review:
Summary and Evaluation

U.S. Fish and Wildlife Service
Southeast Region
Kentucky Ecological Services Field Office
Frankfort, Kentucky

5-YEAR REVIEW

I. GENERAL INFORMATION

A. Methodology used to complete the review

Public notice of initiation of this 5-year review was provided in the *Federal Register* on July 28, 2006 (71 FR 42871) and a 60-day comment period was opened. During this comment period, we obtained information on the status of this species from several experts; additional data was also obtained from the recovery plan, peer-reviewed scientific literature, and our state partners. Once all known literature and information was collected for this species, the review was completed by Leroy Koch, Fish and Wildlife Biologist in the Kentucky Ecological Services Field Office. The draft document was peer-reviewed by Mr. Steve Ahlstedt, retired USGS biologist, Norris, Tennessee; Dr. Monte McGregor, Kentucky Department of Fish and Wildlife Resources (KDFWR), Frankfort, Kentucky; and Mr. Ryan Evans, Kentucky State Nature Preserves Commission. All comments received during the peer review process were incorporated as appropriate.

B. Reviewers

Lead Region -- Kelly Bibb, Southeast Region, Atlanta, GA, 404-679-7132

Lead Field Office -- Leroy Koch, Kentucky Ecological Services Field Office, 502-695-0468

Cooperating Field Offices:
Geoff Call, Cookeville, TN Ecological Services Field Office, 931-528-6481
Jeff Powell, Daphne, AL Ecological Services Field Office, 251-441-5181

Cooperating Region – Mary Parkin, Northeast Region, Hadley, MA, 617-417-3331

Cooperating Field Office:
Shane Hanlon, Abingdon, VA Ecological Services Field Office, 276-623-1233

C. Background

1. **Federal Register Notice citation announcing initiation of this review:** July 28, 2006; 71 FR 42871.

2. **Species status:** Declining
Species continues to be rare and only a few individuals have been observed over the past few years. Only one viable population (Big South

Fork Cumberland River) is believed to exist; all other populations are believed to consist of only remnant individuals. Surveys conducted in 2010 in the Rockcastle River basin (KY) by the KDFWR produced 1 fresh dead individual from Horse Lick Creek, a tributary of the Rockcastle River. No littlewing pearlymussels were observed in the Rockcastle River main stem (total of 10 sites). Based on our analysis, the most significant threats identified in the recovery plan continue to impact the species and only one viable population of the species is believed to exist.

3. **Recovery achieved:** 1 (1 = 0% to 25% of recovery objectives achieved).

4. **Listing history**

Original Listing
FR notice: 53 FR 45861
Date listed: November 14, 1988
Entity listed: species
Classification: endangered

5. **Associated rulemakings**

NA

6. **Review History**

Recovery Plan for Little-wing Pearly Mussel (*Pegias fabula*), 1989, Atlanta, GA

Recovery data call, 1998-2012, U. S. Fish and Wildlife Service

A formal 5-year review of the status of the littlewing pearlymussel was initiated by the Service on November 6, 1991 (56 FR 56882). This review was completed in 1992, and endangered status was maintained for the subspecies based on responses to that review. .

7. **Species' Recovery Priority Number at start of review (48 FR 43098):**

The recovery priority number for this mussel is 4. This indicates a high degree of threat and a low recovery potential.

8. **Recovery Plan**

Name of plan: Recovery Plan for Little-wing Pearly Mussel *(Pegias fabula)*
Date issued: September 22, 1989

II. REVIEW ANALYSIS

A. Application of the 1996 Distinct Population Segment (DPS) policy

The Act defines species as including any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate wildlife. This definition limits listing DPSs to only vertebrate species of fish and wildlife. Because the species under review is an invertebrate, the DPS policy is not applicable.

B. Recovery Criteria

1. Does the species have a final, approved recovery plan containing objective, measurable criteria? Yes

2. Adequacy of recovery criteria.

a. Do the recovery criteria reflect the best available and most up-to-date information on the biology of the species and its habitat? Yes

b. Are all of the 5 listing factors that are relevant to the species addressed in the recovery criteria? Yes

3. List the recovery criteria as they appear in the recovery plan, and discuss how each criterion has or has not been met, citing information.

Downlisting Criteria

The littlewing pearlymussel will be considered for downlisting or reclassification from endangered to threatened status upon completion of the following (USFWS 1989):

1. Through protection of existing populations and successful establishment of reintroduced populations or discovery of additional populations, a total of eight distinct viable populations (see following note) exist in the Cumberland and Tennessee River systems.

2. Biological and ecological studies have been completed, and the recovery measures developed and implemented from these studies are beginning to be successful as evidenced by recruitment and an increase in population density and/or an increase in the population size and length of river reach inhabited within each of the eight populations.

Delisting Criteria

The littlewing pearlymussel will be considered for delisting upon completion of the following (USFWS 1989):

1. Through protection of existing populations and successful establishment of reintroduced populations or discovery of additional populations, a total of 13 distinct viable populations (see following note) exist in the Cumberland and Tennessee River systems.

2. Studies of the mussel's biological and ecological requirements have been completed and recovery measures developed and implemented from these studies have been successful, as evidenced by recruitment and an increase in population density and/or increase in the population size and length of river reach inhabited within each of the 13 populations.

3. No foreseeable threats exist that would likely threaten survival of any of these 13 populations.

4. Where habitat had been degraded, noticeable improvements in water and substratum quality have occurred.

Of the five listing factors, "overutilization for commercial, recreation, scientific, or educational purposes" and "disease or predation" are not relevant to the species and were not addressed by recovery criteria included in the Recovery Plan. We have no new information on either of these listing factors to indicate this has changed; therefore, we do not include further discussion on these two factors in this 5-year review.

***Note**: The Recovery Plan defines a viable population as a reproducing population that is large enough to maintain sufficient genetic variation to enable it to evolve and respond to natural habitat changes. The number of individuals needed to obtain a viable population will be determined as one of the recovery tasks.*

When the recovery plan was completed in 1989, the only viable populations thought to exist occurred in the Big South Fork Cumberland River in Kentucky and Tennessee and in Horselick Creek in Kentucky. Currently, only one viable population remains in the Big South Fork Cumberland River (Steve Ahlstedt, personal communication, USGS retired, 2007; Steve Fraley, personal communication, North Carolina Wildlife Resources Commission 2007; Shane Hanlon, personal communication, U.S. Fish and Wildlife Service, 2007). Except for the population in the Big South Fork Cumberland River (BSFCR), other populations are thought to be extremely small in size, and, in some instances likely represented by a small number of individuals. Extant populations persist in the BSFCR, Rockcastle River, Cane Creek, Clinch River, North Fork Holston River, and Little Tennessee River watersheds. Each of these populations is discussed separately below.

Cumberland River drainage:

a. Big South Fork Cumberland River – At the time of this review, we believe the population of littlewing pearlymussel existing in the BSFCR in Kentucky and Tennessee is the only population within the species' current range that could possibly be considered as 'viable'. At least 102 individuals ranging in size from 10 to 50 millimeters have been recorded from seven sites in both Tennessee and Kentucky since 1999 (Ahlstedt *et al.* 2003-2004). In 2007, one individual was observed at a 'new' location in the BSFCR near the mouth of Troublesome Creek in McCreary County, Kentucky. The BSFCR population is recruiting as evidenced by the varying size of individuals encountered. Additional sampling effort needs to be expended in the BSFCR to better define the extent of this species in the river and identify locations for population enhancement activity. This species is usually difficult to find regardless of the stream in which it occurs, but in the BSFCR it is usually found underneath large rocks in swift water. Although the littlewing pearlymussel population in the BSFCR is the most abundant population known, it is vulnerable to impacts from oil extraction and coal mining, especially from the headwaters of the BSFCR. These activities were considered threats in the recovery plan (i.e. destruction, modification, or curtailment of its habitat or range, inadequacy of existing regulatory mechanisms, and other natural or manmade factors) and still remain as threats to the recovery of this species. Gravid specimens of this species were recently obtained from the BSFCR and taken to the KDFWR's Center for Mollusk Conservation in Frankfort, Kentucky in May 2013. Approximately 1,000 larvae from eight adult females were placed on several potential fish hosts; however, the results of this propagation effort are not completed (Monte McGregor, personal communication May 23, 2013).

b. Little South Fork Cumberland River – When the recovery plan was completed in 1989, this species had just experienced tremendous declines in the Little South Fork Cumberland River (LSFCR), and its status was unclear. Warren and Haag (2005) surveyed this stream in 1997 and 1998 and recorded no live littlewing pearlymussels. Littlewing pearlymussel declines most likely occurred in the lower reaches of the LSFCR due to surface coal mining activity (Anderson *et al.* 1991; Ahlsted and Saylor 1995-1996) and in the upper portion of the LSFCR due to oil extraction (Henry *et al.* 1999). These activities were considered threats in the recovery plan (i.e. destruction, modification, or curtailment of its habitat or range, inadequacy of existing regulatory mechanisms, and other natural or manmade factors) and still remain as threats to the recovery of this species. We believe this species has been extirpated from the LSFCR. Habitat in the LSFCR may not have improved since the events occurred that eliminated the littlewing pearlymussel from this river; consequently, reintroductions may not be appropriate at this time.

c. Rockcastle River - Horselick Creek, a tributary of the Rockcastle River in Kentucky, was mentioned in the recovery plan as having one of the healthiest

surviving populations of the littlewing pearlymussel. An intensive survey effort in 2003 failed to locate this species (Haag and Warren, 2004). This watershed has oil, gas, and coal deposits and the exploration and development of these resources has already begun (USFWS 1989). For unknown reasons, the population in Horselick Creek has declined greatly; however, past coal mining activities have been implicated as a possible cause (Haag and Warren, 2004). These activities were considered threats in the recovery plan (i.e. destruction, modification, or curtailment of its habitat or range, inadequacy of existing regulatory mechanisms, and other natural or manmade factors) and still remain as threats to the recovery of this species. We believe this species still occurs in Horselick Creek; however, the population is likely small enough to be difficult to detect under current mussel sampling efforts and may not be viable. Historically, this species occurred in the mainstem Rockcastle River and may still be present there. A 2010 survey in the Rockcastle River basin by the KDFWR produced 1 fresh dead individual from Horse Lick Creek, a tributary of the Rockcastle River, but no individuals were observed in the Rockcastle River main stem (total of 10 sites).

d. Cane Creek – Cane Creek is located in the Upper Caney Fork River system in Van Buren County, Tennessee. Mr. Jeffrey Simmons (personal communication) collected a live female and a shell of a juvenile female littlewing pearlymussel in Cane Creek in 2005, which was the first collected in Cane Creek since 1985 (Ahlstedt and Saylor 1995-1996). The downstream portion of Cane Creek is impacted by a reservoir, Great Falls Lake. The upstream reach is often subterranean. This river has very limited mussel habitat, and the species is apparently limited to a few shoals immediately upstream of the swinging bridge at Sweetgum, Tennessee (USFWS 1989). Impacts to Cane Creek include cattle in the stream and lack of riparian vegetation (USFWS 1989).

Tennessee River Drainage:

a. Clinch River, Little River (a tributary to the Clinch), and North Fork Holston River – All of these streams are in the Tennessee River drainage in Virginia. This species was last recorded as a single fresh dead specimen from the N. F. Holston River in 2006 (Shane Hanlon, personal communication, USFWS, 2007) and as a single male from the upper Clinch River in 1999 (Jones *et al.* 2001). According to Mr. Hanlon, this species is nearly extirpated in Virginia, and no population of this species in Virginia is considered viable. Primary impacts to this species in Virginia include industrial and municipal pollution, acid mine drainage, and siltation resulting from mining, agriculture, and construction activities (USFWS 1989). These activities were considered threats in the recovery plan (i.e. destruction, modification, or curtailment of its habitat or range, inadequacy of existing regulatory mechanisms, and other natural or manmade factors) and still remain as threats to the recovery of this species.

b. Little Tennessee River in the Tennessee River drainage in North Carolina – Two males of the littlewing pearly mussel were found in the Little Tennessee

River in Swain County, North Carolina in 2005; however, this is not considered a viable population (Steve Fraley, personal communication, North Carolina Wildlife Resources Commission, 2007). Reasons for the decline of this species and other species of the genus Anodontoides in this stream remain unknown. Other mussel species are not impacted to the level of the Anodontoides sp., and the littlewing pearlymussel. Survey efforts since 2005 have failed to reveal causes of this decline; however, there have been increases in development (e.g. subdivisions), gem mining, and the presence of the Asian clam in recent years (Steve Fraley, personal communication, North Carolina Wildlife Resources Commission, 2013).

Studies of this mussel's biological and ecological requirements have not been completed; however, eight females from the BSFCR population were collected in 2001 and used for fish host determination and propagation studies at Virginia Tech in Blacksburg, Virginia. Black sculpins, *Cottus baileyi*, were documented as a successful fish host for the littlewing pearlymussel, and 569 juveniles were released back into the BSFCR in 2002 (Mair *et al.* 2002). The black sculpin is not native to the BSFCR so it is likely another sculpin species serves as host for the BSFCR littlewing pearlymussel population. In 1989, Dr. James Layzer at Tennessee Technological University in Cookeville, Tennessee found that the the greenside darter, *Etheostoma blennioides*, and emerald darter, *Etheostoma baileyi*, also served as fish hosts for the littlewing pearlymussel (Dr. James Layzer, personal communication, Tennessee Technological University, 2007). The Kentucky Department of Fish and Wildlife Resources Center for Mollusk Conservation was successful in propagating and culturing about 25 individuals of this species in 2013 to a size of about 2 to 3 millimeters in length (Monte McGregor, 2103). Instances where this species has been placed into mussel propagation facilities for extended periods have usually resulted in the eventual mortality of captive adult individuals. Currently, much work remains to be done before further progress on downlisting criterion 2 can be considered successful.

We do not anticipate delisting the littlewing pearlymussel in the near future. For most populations, if not all, threats continue to exist at some level. Moreover, no specific information is available to indicate a particular factor, or combination of factors, is causing the decline of the species. Primary threats to this species include industrial and municipal pollution, oil extraction, coal mining, acid mine drainage, and siltation resulting from mining, agriculture, and construction activities (USFWS 1989). Since there is only one viable population of this species known, the BSFCR population, the vulnerability of this population can be considered a threat to this species.

Knowledge of habitat improvements, if any, are either negligible and/or have not been studied well enough to document that the conservation status of the species has improved or habitat degradation has been reversed.

C. Updated Information and Current Species Status

1. Biology and Habitat

Information on biology and habitat can be found in the recovery plan (USFWS 1989).

2. Five-Factor Analysis

Of the five listing factors discussed below, "overutilization for commercial, recreation, scientific, or educational purposes" and "disease or predation" are not thought to be relevant to the species and were not addressed by recovery criteria included in the Recovery Plan. We have no new information on either of these listing factors to indicate this has changed; however, they are included below with brief comments.

Present or threatened destruction, modification or curtailment of its habitat or range: When the recovery plan was completed in 1989, the only viable populations thought to exist occurred in the BSFCR in Kentucky and Tennessee and in Horselick Creek in Kentucky. Currently, only one viable population remains in the Big South Fork Cumberland River (Steve Ahlstedt, personal communication, USGS retired, 2007; Steve Fraley, personal communication, North Carolina Wildlife Resources Commission 2007; Shane Hanlon, personal communication, U.S. Fish and Wildlife Service, 2007). Except for the population in the Big South Fork Cumberland River (BSFCR), other populations are thought to be extremely small in size, and, in some instances, likely represented by a small number of individuals. Extant populations persist in the BSFCR, Rockcastle River, Cane Creek, Clinch River, North Fork Holston River, and Little Tennessee River watersheds, based on the most-recent surveys and observations; however, for all practical purposes, there is only the one viable population – the one in the BSFCR. The recovery plan included habitat loss and water quality deterioration, attributed to impoundments, industrial and municipal pollution, acid mine drainage ,and siltation resulting from mining, agriculture, and construction activities, as the primary reasons for the decline of this species. The current status of this species is likely still attributable to the continued impacts of these threats.

Overutilization for commercial, recreational, scientific, or educational purposes: This species is not believed to be utilized for commercial, recreational, scientific, or educational purposes. Over-collecting does not appear to have become a threat. The small size of this species, the difficulty in being able to find this species, and remoteness of some of the areas it occurs has no doubt helped reduce any of these potential impacts to the species.

Disease or predation: This species is undoubtedly consumed by predators; however, there is no evidence that predation is a significant threat to the species. Disease is not known to be a threat to the species.

Inadequacy of existing regulatory mechanisms: This species and its habitats are afforded some protection from water quality and habitat degradation under the Clean Water Act of 1977 (33 U.S.C. 1251 et seq.), and various state laws and regulations that may provide some level of protection. The species is also afforded protection by the Endangered Species Act (Act) of 1973, as amended (87 Stat. 884, as amended: 16 U.S.C. 1531 *et seq.*), which requires Federal agencies to consult with the Service when activities they fund, authorize, or carry out may affect a listed species. The Act requires Federal permits for any activity that may result in "take" of a listed species.

Despite the limited protection afforded by the laws and corresponding regulations cited above, this species likely continues to be impacted by poor water quality and habitat degradation resulting from siltation and water quality degradation caused by poor land use practices (both historic and current practices), reductions in riparian cover, and by other nonpoint-source pollutants. It is likely that existing regulatory mechanisms have been inadequate to protect the species and its habitat from these types of impacts.

Other natural or manmade factors affecting its continued existence: The restricted range of this species makes its populations much more vulnerable to extirpation from toxic chemical spills, habitat modification, progressive degradation from land surface runoff (nonpoint-source pollutions), and natural catastrophic changes to their habitat (*e.g.*, flood scour, drought). The disjunct nature of populations prohibits the natural interchange of genetic material between existing populations, and the small population sizes observed in most of the remaining populations reduces the reservoir of genetic diversity within populations. It is likely that some of its populations are below the effective population size required to maintain long-term genetic and population viability, with the BSFCR population being the exception. The disjunct nature of the populations also makes the likelihood of recolonization of populations unlikely in the event of an extirpation event, unless human intervention occurs and enables recolonization and/or population augmentation.

Climate change has the potential to increase the vulnerability of this species to random detrimental events. Global climate change is expected to result in increasing frequency and duration of droughts and the strength of storms (e.g., Cook *et al.* 2004). Severe droughts, such as the one that affected Kentucky in 2007 and 2008, may be intensified by the effects of global climate change and result in lower flows and reduced habitat availability for the species.

D. Synthesis

The littlewing pearlymussel is currently restricted to six watersheds in Kentucky, Tennessee, North Carolina, and Virginia: BSFCR, Rockcastle River, Cane Creek, Clinch River, North Fork Holston River, and Little Tennessee River. Unfortunately, the Service believes that the status of the littlewing pearlymussel

has worsened since the recovery plan was published in 1989. For example, recent survey efforts indicate a drastic decline of this species in Horselick Creek, a stream considered as one of the healthiest known populations in 1989. Except for the BSFCR population, all known populations have diminished since the recovery plan was written and now likely consist of only remnant individuals. These populations are not considered to be viable according to the definition of viability presented in the recovery plan. Threats to the species remain similar to those presented in the recovery plan and consist primarily of industrial and municipal pollution, oil extraction, coal mining, acid mine drainage, and siltation resulting from mining, agriculture, and construction activities (USFWS 1989).

The best remaining population of littlewing pearlymussel occurs within the BSFCR in portions of Kentucky and Tennessee. This population has shown evidence of recruitment in recent years and is currently considered the only known viable population. However, the BSFCR population remains vulnerable to impacts from coal mining and oil extraction activities, and additional survey efforts are needed to better define the extent of this species in the river and identify locations that may be appropriate for population enhancement activities.

Limited life history work has been accomplished on this species, but at least three fish species have been determined to serve as suitable hosts. They include the black sculpin, *Cottus baileyi,* greenside darter, *Etheostoma blennioides*, and emerald darter, *E. baileyi*. Some success at rearing juveniles to a few weeks of age before release into the wild has occurred. This species is apparently difficult to maintain alive for extended periods of time in captivity (Dr. Monte McGregor, personal communication, KDFWR, 2007).

Six gravid females were collected for propagation of juveniles in 2004 resulting in a total of 209 juveniles produced; however, all juveniles died by 4 weeks of age (Petty, 2007). Survival of these juveniles likely was poor due to the use of immature glochidia. Propagation efforts are ongoing at the KDFWR's Center for Mollusk Conservation in Frankfort, Kentucky using gravid females from a recent collection (see section on BSFCR above).

The recovery criteria have not been fully met for downlisting this mussel species. The single viable population in the BSFCR, and the limited work regarding fish host identification and juvenile propagation can only be considered a very small step towards meeting recovery criteria. Because of the restricted distribution of the species (i.e., only viable population known is in a portion of the BSFCR in Tennessee and Kentucky), extirpation and decline of most populations (e.g., most recent documented example is Horselick Creek), continued potential threats (e.g., industrial and municipal pollution, oil extraction, coal mining, acid mine drainage, and siltation resulting from mining, agriculture, and construction activities), and lack of evidence showing achievement of recovery criteria (i.e., no successful propagation and/or culture efforts), we believe that the status of littlewing pearlymussel should remain as endangered.

III. RESULTS

A. Recommended Classification:

__X__ **No change is needed**

IV. RECOMMENDATIONS FOR FUTURE ACTIONS

Recommendations for high priority future recovery actions include the following:

1. Conduct a thorough survey of the Big South Fork Cumberland River in Kentucky and Tennessee to better determine the status and extent of this species. This cryptic species is difficult to locate regardless of where it occurs. In the BSFCR, it is usually found beneath large rocks in swift water.

2. Conduct extensive surveys of the mainstem Rockcastle River and portions of selected tributaries, including Horselick Creek, to determine the status of the species in this drainage, and to determine if suitable habitat and water conditions exist in the Rockcastle River drainage in which to translocate adults and/or locate propagated juveniles.

3. Take appropriate actions to eliminate or greatly diminish threats to this species at all known locations, especially the Big South Fork Cumberland River and the Rockcastle River drainages. Regulations that apply to coal mining and oil extraction activities need to be strictly enforced to prevent the loss of these populations.

4. Successfully propagate and culture this species in captivity. Past efforts have met with poor results (i.e., juveniles produced died); however, current efforts are ongoing and are expected to be more successful.

5. Enhance the population in the Big South Fork Cumberland River through introduction of propagated juveniles.

6. Create at least one new viable population elsewhere than in the Big South Fork Cumberland River.

V. REFERENCES

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Experts consulted include the following:

Dr. Monte McGregor, Kentucky Department of Fish and Wildlife Resources, Malacologist, served as a peer reviewer.

Mr. Steve Ahlstedt, retired USGS biologist, has extensive experience working with this species. He served as a peer reviewer and provided information.

Mr. Ryan Evans, Kentucky State Nature Preserves Commission, Aquatic Biologist, served as peer reviewer.

Mr. Steve Fraley, North Caroline Wildlife Resources Commission, provided information.

Mr. Jeffrey Wade, Tennessee Valley Authority, provided information.

U.S. FISH AND WILDLIFE SERVICE
5-YEAR REVIEW of Littlewing pearlymussel, *Pegias fabula*

Current Classification Endangered
Recommendation resulting from the 5-Year Review

____ **Downlist to Threatened**
____ **Uplist to Endangered**
____ **Delist**
_X_ **No change is needed**

Review Conducted By Mr. Leroy Koch, Kentucky Ecological Services Field Office

FIELD OFFICE APPROVAL:

Lead Field Supervisor, Fish and Wildlife Service

Approve _____ Date 8/17/13

REGIONAL OFFICE APPROVAL:

Lead Regional Director, Fish and Wildlife Service

Approve_____Date_____

Cooperating Regional Director, Fish and Wildlife Service

_____Concur _____ Do Not Concur

Signature_____Date_____

APPENDIX A: Summary of peer review for the 5-year review of littlewing pearlymussel (*Pegias fabula*)

A. Peer Review Method: *Provide information on any peer review methods or processes used, including type of peer review.*

Peer review was conducted by sending out an email asking Mr. Steve Ahlstedt, retired USGS biologist, Norris, Tennessee; Dr. Monte McGregor, Kentucky Department of Fish and Wildlife Resources, Frankfort, Kentucky; and Mr. Ryan Evans, Kentucky State Nature Preserves Commission to review the draft 5-year review (these individuals are considered to be species' experts).

B. Peer Review Charge:
Peer reviewers were asked to comment on the validity of the data used and identification of any additional information that was not considered in the draft review. Reviewers were not asked to comment on the legal status of the species.

C. Summary of Peer Review Comments/Report:
Peer reviews were mainly editorial in nature with very minor comments to the content. Peer reviewers thought it was complete and presented the data fairly.

D. Response to Peer Review:
Peer review comments were evaluated and incorporated into the 5-year review as appropriate.