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After the Board of Inquiry ruled against NutraSweet on Sept. 30, 1980, Searle waited until Jan. 21, 1981, the day after President Reagan's inauguration, to press for a reversal of the FDA commissioner - assuring the new administration would decide the issue.

Jere Goyan, Hayes' predecessor as commissioner, said he found the delay curious because, after eight years of legal battles, financially struggling Searle "obviously was most anxious to have this thing approved."

Robert Dormer, a lawyer for The NutraSweet Co., said there was nothing special about the Jan. 21 date or the papers filed that day.

But with Reagan's election, it was virtually assured that a Republican-appointed commissioner would replace Goyan and decide the appeal -- and Searle had strong GOP connections with Rumsfeld at the helm.

Goyan had set up a five-member "commissioner's team" of scientists with no prior involvement in the issue to review the board's ruling.

On May 18 and 19, 1981, a month after Hayes took office, scientists Satya Dubey, Douglas Park and Robert Condon each laid out concerns about the sweetener's safety in memos to team lawyer Joseph Levitt.

Dubey not only expressed reservations about the reported incidence of brain tumors in one key Searle rat study, but also said key data in another study appeared to have been altered. Dubey, who still works at FDA, refuses to discuss the matter.

Condon, another statistician on the team, and Park, staff science adviser in the agency's Office of Health Affairs, each said the available evidence failed to prove NutraSweet's safety or lack of safety.

Park said that Levitt hurried the panel to decide the issue. "They wanted to have the results yesterday," he said. "We really didn't have the time to do the in-depth review we wanted to do."

Park said Levitt met frequently with Hayes and "was obviously getting the pressure to get a resolution and a decision made."

Sources have said the office of Sen. Howard Metzenbaum, D-Ohio, has received allegations of political influence in Hayes' final decision-making process.

In a letter written after the FDA cleared NutraSweet, one former Searle saleswoman, **Patty Wood-Allott,** asserted that Rumsfeld told his sales force shortly after Reagan took office that, if necessary, "he would call in all his markers and that no matter what he would see to it that aspartame would be approved that year." Rumsfeld declined to return phone calls.

With three of five scientists on the commissioner's team opposing approval, it was decided to bring in a toxicologist

for his opinion on isolated issues.

Goyan said if the decision were his, he never would have enlarged the team. While the panel did not vote, it ended up split 3-3.

Levitt, who normally would have been expected to draft an options paper spelling out scientific evidence on key issues, took an unusual tack. He circulated an approval recommendation -- and only backed off when Dubey, Park and Condon objected, team members said.

Levitt said he was not directed to draft the approval memo, but did so as a "tactical" step to break the team's weeks-long impasse by forcing each scientist to state his views.

"It worked, didn't it?" said Levitt, who later was promoted to a post as an executive assistant to the FDA commissioner.

One team member said that during discussions, Hayes, appeared to be abandoning the agency's traditional standard of "reasonable" proof of safety and looking for "proof of hazard."

Hayes' July 1981 approval decision came in the face of a Searle threat to file a suit challenging the regulatory delays.

His ruling relied in part on a late rat study of brain tumors submitted by Ajinomoto, a Japanese company that manufactures aspartame for Searle. That study, however, tested Wistar rats, a strain that some scientists said is more tumor resistant than the Sprague-Dawley rats used in earlier research.

In his decision, Hayes wrote: "Few compounds have withstood such detailed testing and the repeated close scrutiny and the process through which aspartame has gone should provide the public with confidence of its safety."

In late 1982, Searle petitioned for FDA approval to use the sweetener in diet soft drinks and children's vitamins. On a day when Hayes was away, Novitch approved the petition, increasing the acceptable daily intake level for humans by nearly half, from 34 to 50 milligrams per kilogram of body weight.

Novitch, now in private industry, said he and Hayes had worked together on the matter, but declined to say why he was left to sign the approval.

Just weeks later, Hayes resigned under the cloud of an internal Department of Health and Human Services investigation into his acceptance of gratuities from FDA-regulated companies -- including free rides aboard jets owned by a major NutraSweet user, the General Foods Corp.

Shortly after being named dean of the New York Medical School, Hayes also became a consultant to the New York-based public relations firm of Burson Marsteller, which represents the NutraSweet Co. and several major users.

Hayes' former top spokesman, Wayne Pines, who previously had joined the firm, said he approached Hayes because he thought him "an added value" to clients.

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